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# PROVISIONAL APPLICATION FOR PATENT COVER SHEET

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**TITLE OF THE INVENTION (500 characters max)**

METHOD AND APPARATUS FOR A FLUID SAMPLING DEVICE AND IMPROVEMENTS

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**ENCLOSED APPLICATION PARTS (check all that apply)**

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☑ Application Data Sheet. See 37 CFR 1.76

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Respectfully submitted,

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# *PROVISIONAL APPLICATION COVER SHEET*
*Additional Page*

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Attorney Docket No.: 38187-2687

# PROVISIONAL PATENT APPLICATION

# METHOD AND APPARATUS FOR A FLUID SAMPLING DEVICE AND IMPROVEMENTS


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# METHOD AND APPARATUS FOR A FLUID SAMPLING DEVICE AND IMPROVEMENTS

## BACKGROUND OF THE INVENTION

Lancing devices are known in the medical health-care products industry for piercing the skin to produce blood for analysis. Typically, a drop of blood for this type of analysis is obtained by making a small incision in the fingertip, creating a small wound, which generates a small blood droplet on the surface of the skin.

Early methods of lancing included piercing or slicing the skin with a needle or razor. Current methods utilize lancing devices that contain a multitude of spring, cam and mass actuators to drive the lancet. These include cantilever springs, diaphragms, coil springs, as well as gravity plumbs used to drive the lancet. The device may be held against the skin and mechanically triggered to ballistically launch the lancet. Unfortunately, the pain associated with each lancing event using known technology discourages patients from testing. In addition to vibratory stimulation of the skin as the driver impacts the end of a launcher stop, known spring based devices have the possibility of firing lancets that harmonically oscillate against the patient tissue, causing multiple strikes due to recoil. This recoil and multiple strikes of the lancet is one major impediment to patient compliance with a structured glucose monitoring regime.

Success rate generally encompasses the probability of producing a blood sample with one lancing action, which is sufficient in volume to perform the desired analytical test. The blood may appear spontaneously at the surface of the skin, or may be "milked" from the wound. Milking generally involves pressing the side of the digit, or in proximity of the wound to express the blood to the surface. In traditional methods, the blood droplet produced by the lancing action must reach the surface of the skin to be viable for testing.

When using existing methods, blood often flows from the cut blood vessels but is then trapped below the surface of the skin, forming a hematoma. In other instances, a wound is created, but no blood flows from the wound. In either case, the lancing process cannot be combined with the sample acquisition and testing step. Spontaneous blood droplet generation with current mechanical launching system varies between launcher

types but on average it is about 50% of lancet strikes, which would be spontaneous. Otherwise milking is required to yield blood. Mechanical launchers are unlikely to provide the means for integrated sample acquisition and testing if one out of every two strikes does not yield a spontaneous blood sample.

Many diabetic patients (insulin dependent) are required to self-test for blood glucose levels five to six times daily. The large number of steps required in traditional methods of glucose testing ranging from lancing, to milking of blood, applying blood to the test strip, and getting the measurements from the test strip discourages many diabetic patients from testing their blood glucose levels as often as recommended. Tight control of plasma glucose through frequent testing is therefore mandatory for disease management. The pain associated with each lancing event further discourages patients from testing. Additionally, the wound channel left on the patient by known systems may also be of a size that discourages those who are active with their hands or who are worried about healing of those wound channels from testing their glucose levels.

Another problem frequently encountered by patients who must use lancing equipment to obtain and analyze blood samples is the amount of manual dexterity and hand-eye coordination required to properly operate the lancing and sample testing equipment due to retinopathies and neuropathies particularly, severe in elderly diabetic patients. For those patients, operating existing lancet and sample testing equipment can be a challenge. Once a blood droplet is created, that droplet must then be guided into a receiving channel of a small test strip or the like. If the sample placement on the strip is unsuccessful, repetition of the entire procedure including re-lancing the skin to obtain a new blood droplet is necessary.

Measurement of glucose concentration is commonly based on the use of an enzyme such as glucose oxidase or glucose dehydrogenase. In such sensing schemes, glucose (substrate) is turned over by an enzyme layer resulting in change in the concentration of another species such as oxygen or hydrogen ion. The change in concentration of these species can be converted into some charge based or optical change at a transducer interface (sensing region). Alternatively, if the enzyme is electrically coupled to an inert electrode, such a reaction results in a change in electron flow at constant applied potential. Both types of transduction mechanisms are widely used in glucose sensing. In the former type of transduction scheme, the reaction zone can be decoupled from the sensing region. Thus, the reaction of the enzyme with the substrate

can be brought about in one region and the concentration measurement can be done in another region. In the latter scheme, the enzymatic reaction has to occur in close proximity to the sensing region (electrode surface) for electrical coupling. Some devices may also include sensor for analyzing sample fluid. Unfortunately, the storage ability of these devices are limited due to the need for some of these elements to be stored in inert environments.

The current sensing technologies do not attempt the separate the reaction zone from the sensing region. One disadvantage of this approach is that the enzyme layer has to be placed in close proximity to the sensing element. This results in considerable difficulty in manufacturing and/or stabilizing the chemistries associated with enzymatic reaction and the transduction scheme. For example in the optical transduction schemes, an oxygen sensing layer such as a silicone rubber film doped with a flurophore, such as Ru Tris Diphenyl Phenanthroline, is coupled to the enzymatic layer containing glucose oxidase. The chemicals used in making these layers interfere with proper functioning of each other. There is often considerable reduction in the enzyme activity. The resultant sensors have limited dynamic range or limited shelf life or both.

## SUMMARY OF THE INVENTION

The present invention provides solutions for at least some of the drawbacks discussed above. Specifically, some embodiments of the present invention provide an improved fluid sampling device. To improve shelf stable storage, devices and methods for decoupling enzyme layer from the sensing region may be provided. What is desired is a device and method that decouples the enzymatic reaction zone from the sensing region while providing appropriate contacting of the two with the sample to be analyzed. At least some of these and other objectives described herein will be met by embodiments of the present invention.

In one aspect of the present invention, the invention relates to using the electronic tissue penetration device to drive a penetrating member into tissue, causing two separated storage areas to be opened during actuation.

In one embodiment of the present invention, a method of body fluid sampling is provided. The method comprises moving a penetrating member at conforming to a selectable velocity profile or motion waveform; piercing a storage area having a sensing area; piercing another storage area having an enzyme area separate from the sensing area

prior to piercing; and causing fluid to first flow to the enzyme area and then to the sensing area. The method may further comprise storing said enzyme area in an inert environment different from an environment for the sensing area. Various configuration of cartridges for use with such a device are shown.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

## DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention provides a solution for body fluid sampling. Specifically, some embodiments of the present invention provides a method for improving spontaneous blood generation. The invention may use a high density penetrating member design. It may use penetrating members of smaller size, such as but not limited to diameter or length, than those of conventional penetrating members known in the art. The device may be used for multiple lancing events without having to remove a disposable from the device. The invention may provide improved sensing capabilities. At least some of these and other objectives described herein will be met by embodiments of the present invention.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed. It may be noted that, as used in the specification and the appended claims, the singular forms "a", "an" and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a material" may include mixtures of materials, reference to "a chamber" may include multiple chambers, and the like. References cited herein are hereby incorporated by reference in their entirety, except to the extent that they conflict with teachings explicitly set forth in this specification.

In this specification and in the claims which follow, reference will be made to a number of terms which shall be defined to have the following meanings:

"Optional" or "optionally" means that the subsequently described circumstance may or may not occur, so that the description includes instances where the circumstance occurs and instances where it does not. For example, if a device optionally contains a feature for analyzing a blood sample, this means that the analysis feature may or may not

be present, and, thus, the description includes structures wherein a device possesses the analysis feature and structures wherein the analysis feature is not present.

The present invention may be used with a variety of different penetrating member drivers. It is contemplated that these penetrating member drivers may be spring based, solenoid based, magnetic driver based, nanomuscle based, or based on any other mechanism useful in moving a penetrating member along a path into tissue. It should be noted that the present invention is not limited by the type of driver used with the penetrating member feed mechanism. One suitable penetrating member driver for use with the present invention is shown in Figure 1. This is an embodiment of a solenoid type electromagnetic driver that is capable of driving an iron core or slug mounted to the penetrating member assembly using a direct current (DC) power supply. The electromagnetic driver includes a driver coil pack that is divided into three separate coils along the path of the penetrating member, two end coils and a middle coil. Direct current is alternated to the coils to advance and retract the penetrating member. Although the driver coil pack is shown with three coils, any suitable number of coils may be used, for example, 4, 5, 6, 7 or more coils may be used.

Referring to the embodiment of Figure 1, the stationary iron housing 10 may contain the driver coil pack with a first coil 12 flanked by iron spacers 14 which concentrate the magnetic flux at the inner diameter creating magnetic poles. The inner insulating housing 16 isolates the penetrating member 18 and iron core 20 from the coils and provides a smooth, low friction guide surface. The penetrating member guide 22 further centers the penetrating member 18 and iron core 20. The penetrating member 18 is protracted and retracted by alternating the current between the first coil 12, the middle coil, and the third coil to attract the iron core 20. Reversing the coil sequence and attracting the core and penetrating member back into the housing retracts the penetrating member. The penetrating member guide 22 also serves as a stop for the iron core 20 mounted to the penetrating member 18.

As discussed above, tissue penetration devices which employ spring or cam driving methods have a symmetrical or nearly symmetrical actuation displacement and velocity profiles on the advancement and retraction of the penetrating member as shown in Figures 2 and 3. In most of the available lancet devices, once the launch is initiated, the stored energy determines the velocity profile until the energy is dissipated. Controlling impact, retraction velocity, and dwell time of the penetrating member within

the tissue can be useful in order to achieve a high success rate while accommodating variations in skin properties and minimize pain. Advantages can be achieved by taking into account of the fact that tissue dwell time is related to the amount of skin deformation as the penetrating member tries to puncture the surface of the skin and variance in skin deformation from patient to patient based on skin hydration.

In this embodiment, the ability to control velocity and depth of penetration may be achieved by use of a controllable force driver where feedback is an integral part of driver control. Such drivers can control either metal or polymeric penetrating members or any other type of tissue penetration element. The dynamic control of such a driver is illustrated in Figure. 2C which illustrates an embodiment of a controlled displacement profile and Figure 2D which illustrates an embodiment of a the controlled velocity profile. These are compared to Figures 2A and 2B, which illustrate embodiments of displacement and velocity profiles, respectively, of a harmonic spring/mass powered driver. Reduced pain can be achieved by using impact velocities of greater than about 2 m/s entry of a tissue penetrating element, such as a lancet, into tissue. Other suitable embodiments of the penetrating member driver are described in commonly assigned, copending U.S. Patent Application Ser. No. 10/127,395, (Attorney Docket No. 38187-2551) filed April 19, 2002 and previously incorporated herein.

Figure 3 illustrates the operation of a feedback loop using a processor 60. The processor 60 stores profiles 62 in non-volatile memory. A user inputs information 64 about the desired circumstances or parameters for a lancing event. The processor 60 selects a driver profile 62 from a set of alternative driver profiles that have been preprogrammed in the processor 60 based on typical or desired tissue penetration device performance determined through testing at the factory or as programmed in by the operator. The processor 60 may customize by either scaling or modifying the profile based on additional user input information 64. Once the processor has chosen and customized the profile, the processor 60 is ready to modulate the power from the power supply 66 to the penetrating member driver 68 through an amplifier 70. The processor 60 may measure the location of the penetrating member 72 using a position sensing mechanism 74 through an analog to digital converter 76 linear encoder or other such transducer. Examples of position sensing mechanisms have been described in the embodiments above and may be found in the specification for commonly assigned, copending U.S. Patent Application Ser. No. 10/127,395, (Attorney Docket No. 38187-

2551) filed April 19, 2002 and previously incorporated herein. The processor 60 calculates the movement of the penetrating member by comparing the actual profile of the penetrating member to the predetermined profile. The processor 60 modulates the power to the penetrating member driver 68 through a signal generator 78, which may control the amplifier 70 so that the actual velocity profile of the penetrating member does not exceed the predetermined profile by more than a preset error limit. The error limit is the accuracy in the control of the penetrating member.

After the lancing event, the processor 60 can allow the user to rank the results of the lancing event. The processor 60 stores these results and constructs a database 80 for the individual user. Using the database 79, the processor 60 calculates the profile traits such as degree of painlessness, success rate, and blood volume for various profiles 62 depending on user input information 64 to optimize the profile to the individual user for subsequent lancing cycles. These profile traits depend on the characteristic phases of penetrating member advancement and retraction. The processor 60 uses these calculations to optimize profiles 62 for each user. In addition to user input information 64, an internal clock allows storage in the database 79 of information such as the time of day to generate a time stamp for the lancing event and the time between lancing events to anticipate the user's diurnal needs. The database stores information and statistics for each user and each profile that particular user uses.

In addition to varying the profiles, the processor 60 can be used to calculate the appropriate penetrating member diameter and geometry suitable to realize the blood volume required by the user. For example, if the user requires about 1-5 microliter volume of blood, the processor 60 may select a 200 micron diameter penetrating member to achieve these results. For each class of lancet, both diameter and lancet tip geometry, is stored in the processor 60 to correspond with upper and lower limits of attainable blood volume based on the predetermined displacement and velocity profiles.

The lancing device is capable of prompting the user for information at the beginning and the end of the lancing event to more adequately suit the user. The goal is to either change to a different profile or modify an existing profile. Once the profile is set, the force driving the penetrating member is varied during advancement and retraction to follow the profile. The method of lancing using the lancing device comprises selecting a profile, lancing according to the selected profile, determining lancing profile traits for

each characteristic phase of the lancing cycle, and optimizing profile traits for subsequent lancing events.

Figure 4 illustrates an embodiment of a tissue penetration device, more specifically, a lancing device 80 that includes a controllable driver 179 coupled to a tissue penetration element. The lancing device 80 has a proximal end 81 and a distal end 82. At the distal end 82 is the tissue penetration element in the form of a penetrating member 83, which is coupled to an elongate coupler shaft 84 by a drive coupler 85. The elongate coupler shaft 84 has a proximal end 86 and a distal end 87. A driver coil pack 88 is disposed about the elongate coupler shaft 84 proximal of the penetrating member 83. A position sensor 91 is disposed about a proximal portion 92 of the elongate coupler shaft 84 and an electrical conductor 94 electrically couples a processor 93 to the position sensor 91. The elongate coupler shaft 84 driven by the driver coil pack 88 controlled by the position sensor 91 and processor 93 form the controllable driver, specifically, a controllable electromagnetic driver.

Referring to Figure 5, the lancing device 80 can be seen in more detail, in partial longitudinal section. The penetrating member 83 has a proximal end 95 and a distal end 96 with a sharpened point at the distal end 96 of the penetrating member 83 and a drive head 98 disposed at the proximal end 95 of the penetrating member 83. A penetrating member shaft 201 is disposed between the drive head 98 and the sharpened point 97. The penetrating member shaft 201 may be comprised of stainless steel, or any other suitable material or alloy and have a transverse dimension of about 0.1 to about 0.4 mm. The penetrating member shaft may have a length of about 3 mm to about 50 mm, specifically, about 15 mm to about 20 mm. The drive head 98 of the penetrating member 83 is an enlarged portion having a transverse dimension greater than a transverse dimension of the penetrating member shaft 201 distal of the drive head 98. This configuration allows the drive head 98 to be mechanically captured by the drive coupler 85. The drive head 98 may have a transverse dimension of about 0.5 to about 2 mm.

A magnetic member 102 is secured to the elongate coupler shaft 84 proximal of the drive coupler 85 on a distal portion 203 of the elongate coupler shaft 84. The magnetic member 102 is a substantially cylindrical piece of magnetic material having an axial lumen 204 extending the length of the magnetic member 102. The magnetic member 102 has an outer transverse dimension that allows the magnetic member 102 to slide easily within an axial lumen 105 of a low friction, possibly lubricious, polymer

guide tube 105' disposed within the driver coil pack 88. The magnetic member 102 may have an outer transverse dimension of about 1.0 to about 5.0 mm, specifically, about 2.3 to about 2.5 mm. The magnetic member 102 may have a length of about 3.0 to about 5.0 mm, specifically, about 4.7 to about 4.9 mm. The magnetic member 102 can be made from a variety of magnetic materials including ferrous metals such as ferrous steel, iron, ferrite, or the like. The magnetic member 102 may be secured to the distal portion 203 of the elongate coupler shaft 84 by a variety of methods including adhesive or epoxy bonding, welding, crimping or any other suitable method.

Proximal of the magnetic member 102, an optical encoder flag 206 is secured to the elongate coupler shaft 84. The optical encoder flag 206 is configured to move within a slot 107 in the position sensor 91. The slot 107 of the position sensor 91 is formed between a first body portion 108 and a second body portion 109 of the position sensor 91. The slot 107 may have separation width of about 1.5 to about 2.0 mm. The optical encoder flag 206 can have a length of about 14 to about 18 mm, a width of about 3 to about 5 mm and a thickness of about 0.04 to about 0.06 mm.

The optical encoder flag 206 interacts with various optical beams generated by LEDs disposed on or in the position sensor body portions 108 and 109 in a predetermined manner. The interaction of the optical beams generated by the LEDs of the position sensor 91 generates a signal that indicates the longitudinal position of the optical flag 206 relative to the position sensor 91 with a substantially high degree of resolution. The resolution of the position sensor 91 may be about 200 to about 400 cycles per inch, specifically, about 350 to about 370 cycles per inch. The position sensor 91 may have a speed response time (position/time resolution) of 0 to about 120,000 Hz, where one dark and light stripe of the flag constitutes one Hertz, or cycle per second. The position of the optical encoder flag 206 relative to the magnetic member 102, driver coil pack 88 and position sensor 91 is such that the optical encoder 91 can provide precise positional information about the penetrating member 83 over the entire length of the penetrating member's power stroke.

An optical encoder that is suitable for the position sensor 91 is a linear optical incremental encoder, model HEDS 9200, manufactured by Agilent Technologies. The model HEDS 9200 may have a length of about 20 to about 30 mm, a width of about 8 to about 12 mm, and a height of about 9 to about 11 mm. Although the position sensor 91 illustrated is a linear optical incremental encoder, other suitable position sensor

embodiments could be used, provided they posses the requisite positional resolution and time response. The HEDS 9200 is a two channel device where the channels are 90 degrees out of phase with each other. This results in a resolution of four times the basic cycle of the flag. These quadrature outputs make it possible for the processor to determine the direction of penetrating member travel. Other suitable position sensors include capacitive encoders, analog reflective sensors, such as the reflective position sensor discussed above, and the like.

A coupler shaft guide 111 is disposed towards the proximal end 81 of the lancing device 80. The guide 111 has a guide lumen 112 disposed in the guide 111 to slidingly accept the proximal portion 92 of the elongate coupler shaft 84. The guide 111 keeps the elongate coupler shaft 84 centered horizontally and vertically in the slot 102 of the optical encoder 91.

In another aspect of the present invention, a still further embodiment of a body fluid sampling device will now be described. Additional details of a suitable body fluid sampling device can be found in commonly assigned, copending U.S. Patent Application Ser. No. ________ (Attorney Docket No. 38187-2662) filed May 1, 2003, fully incorporated by reference for all purposes.

Referring now to Figure 6, one embodiment of a sampling device 220 is shown. In this embodiment, a cartridge 222 have a disc shape may be used to house a plurality fo penetrating members 224 that may extend outward from an opening 226. A finger or other tissue may be placed at interface 228. It should be understood that a variety of different penetrating members may be used including but not limited to solid, elongate members or patent needle members. In this embodiment, a penetrating member driver 230 may be used to individually engage each penetrating member 224. The penetrating member driver 230 may include those described herein those described in commonly assigned, copending U.S. Patent Application Ser. No. ________ (Attorney Docket No. 38187-2551) filed April 19, 2002 or (Attorney Docket No. 38187-2663) filed_____, each fully incorporated by reference for all purposes

Referring now to Figure 7, a still further embodiment of a fluid sampling device 240 is shown. In this embodiment, a cartridge 242 is shown which may be inserted into the underside of the device 240. A front end 244 is shown. In this embodiment a solenoid may be used as the penetrating member driver. It should be understood that Figure 7 shows an exploded view of the components used in the present embodiment. A

visual display 246 may be used for various reasons including but not limited to relaying information to the user, to display lancing performance, to provide device status, and other information as described in commonly assigned, copending U.S. Patent Application Ser. No. _______ (Attorney Docket No. 38187-2595) filed __________ and Attorney Docket No. 38187-2634, fully incorporated herein by reference.

Referring now to Figures 8 and 9, top and bottom view of a chassis 250 for use with the device 240 is shown in further detail. Figure 8 shows various toothed surfaces 252. Figure 9 shows an underside with a recessed portion 254 for receiving a cartridge 242. The cartridge 242 may be rotated or indexed based on movement of the slider 256 (see Figure 7).

Referring now to Figure 10, various cross-sectional views of one embodiment of a cartridge 242 according to the present invention is shown. It should be understood that the cartridge 242 may include a sterility barrier (not shown in Figure 10 for ease of illustration). It should be understood that all measurements and dimensions shown in Figure 10 are purely exemplary and other sizes may be used without departing from the spirit of the present invention. It should be understood that the dimensions near cross-section D are such that, in this embodiment, the penetrating member may be gripped or held in place by the cartridge, preventing the penetrating member from extending outward.

Referring now to Figures 11, 12, and 13, top down, side and bottom view of the cartridge 242 are shown. Again, all dimensions are purely exemplary and other sizes may be used or varied without departing from the spirit of the present invention. As seen the cartridge 242 may include a notch 260 on the outer perimeter (Figure 13). This may be used for positioning of the cartridge 242 into the device. It may also be used for counting purposes, by tracking where this notch is, relative to the device 240, the number of penetrating members remaining may be calculated. The notch 260, in another device, maybe be used to align the cartridge 242 on a rotating disc or surface, where rotation of the surface is used to track the position of the cartridge 242 and the number of penetrating members remaining. As seen in Figures 12 and 13, the inner diameter may include notches 262 for position purposes and for purposes of turning or rotating the cartridge 242.

Referring now to Figure 14, a perspective view of an embodiment of the cartridge 242 is shown. As seen in Figure 14, penetrating members 224 are shown housed in the

cartridge 242. Figure 14 also shows an embodiment where a toothed surface 264 is included on the inner circumference of the cartridge 242.

Referring now to Figure 15, a still further embodiment of a cartridge according to the present invention will be described. As seen in Figure 15, this embodiment has a cartridge 270 with a sterility barrier 272 and a sensor layer 274. As seen Figure 15, the sensor layer 274 has a plurality of leads 276 which extend from sensor 278. In one embodiment, these leads 276 extend to the inner circumference to connect to couplers (not shown) the sampling device 240. As seen on layer 272, an arrow 273, triangle, circle, dot, square, or other orientation marker may be on the layer 272 or in other embodiments on the cartridge 270 (or cartridge 242) or on the layer 274 to facilitate positioning by the user.

Referring now to Figure 16, a top down view is shown of one embodiment of the sensor layer 274. It should be understood the leads 276 may also be configured to extend short of the inner diameter. For ease of illustration, various configurations are shown on the same sensor layer 274. It should be understood that the leads on the sensor layer 274 may all have the same configuration, any combination of the configurations shown herein, or other configurations. The leads 280 may extend roughly halfway while leads 282 extend further. They may then engage various contact pads (not shown) on the device 240 which can engage the leads. A still further embodiment has leads 284 that extend towards the outer circumference of the cartridge 242 to engage various contact pads or other connectors as known to those of skill in the art.

Referring now to Figure 17, a still further embodiment of the present invention will be described. As seen in this embodiment, various visual markings may be made on the top surface and/or the bottom surface of the cartridge 290. Figure 17 only shows the top side of the cartridge 290, however, these same markings may also be made on the underside. Although not limited to the following, these markings may be in the form of colors, numbers, bar codes, or other markings. The embodiment in Figure 17 shows a region 292 that may be warning region indicating to the user that number of unused penetrating members are running low. The region 294 may be used to indicate that the penetrating members are almost all used. Although not limited to the following, these regions 294 may be color coded. The regions may also have certain properties that may be detectable by other sensors, such as but not limited to being magnetic or having other detectable properties. In some embodiments, the markings maybe be on portions directly

opposite of the active region since the window 296 may be on the side of the cartridge that is not the active side. These markings may cover only a portion of the cartridge or the entire cartridge may contain markings that provide information. Binary or other machine readable information may also be placed on the cartridge and then detected by a reader in the device 240 for detecting status information based on how the cartridge is positioned.

Referring now to Figure 18, a still further embodiment of a cartridge according to the present invention will be described. For ease of illustration, multiple elements are shown on the cartridge 300. It should be understood that the cartridge 300 and others described herein may include some, none, or all of these features. This cartridge may include a dessicant 302 that may be included in the cartridge 300 to absorb moisture that may enter therein. Dessicant 302 may be in the form of a pellet or other embodiment that is a separate element from the cartridge. In other embodiments, the dessicant 304 may be printed, deposited, or otherwise integrated to the cartridge 300. The dessicant 306 may be on the side surfaces of cavities in the cartridge 300. A still further embodiment has the dessicant 308 attached by some technique such as, but not limited to printing, adhering, forming, or other wise integrating the dessicant 308 to some material coupled to the cartridge, such as but not limited to the sterility barrier. These techniques may also be used to attach these dessicants to the cartridge or even the sensor layer. They may also be coupled to a separate layer of material attached to the cartridge that only covers a portion of the cartridge.

A still further feature of the cartridge 300 is to include a separate test that the cartridge 300 may be rotated to if the processor on the device detects that the analyte readings from a regular test requires a specialized test to be conducted. The cartridge 300 will be rotated as indicated by arrow 309. As a nonlimiting example, if glucose readings are detected outside a desired range, a processor may recommend a HB1AC test be conducted. The cartridge 300 may then be rotated to designated position to align a cavity 310 with a sensor 312 for this test. This rotation may occur by mechanical actuation or by electric powered rotation of the cartridge. In this embodiment, each cartridge may have three HB1AC tests. Other cartridges may have other numbers or they may have other test areas in place of the HB1AC tests.

Referring now to Figure 19, a still further embodiment of penetrating member coupler will now be described. In this embodiment, the coupler 320 is linked to an

electrical source 322 that can be controlled to release a charge to sterilize a penetrating member coupled to the coupler 320. Thus, prior to use, the coupler 320 can sterilize the penetrating member before the member is driven into tissue.

Figure 19 also shows a heating element 326 that may be used to melt a portion of the cartridge after the penetrating member has been actuated. This will hold the penetrating member in place and prevent the sharp from being released from the cartridge. The heating element 326 may be positioned at a cavity adjacent or in other embodiments, simply away from the active cavity. In other embodiments, the heating element 326 (shown in phantom) may be positioned over the activity cavity.

Referring now to Figure 20, a still further embodiment of the present invention may use a processor 330 to detect the amount of force used a cutter 332 or a punch 334 to pierce the sterility barrier on the cartridge. Although not limited to the following, the amount of force may be used to detect if the cavity on the cartridge is a used and the sterility barrier has already been breached.

Referring now to Figure 21, a still further embodiment of the present invention will now be described. As seen in Figure 21, one embodiment of a cartridge 340 according to the present invention may not have a opening in the center like those cartridges shown in the previous figures. Figure 21 also shows various receptacles 342 and 344 shown in phantom. In this embodiment, the penetrating members are not parked in the cartridge after use. They may be actuated and then released. They may fall into container 344 through a slot in the bottom of the cartridge. Or they be dumped into the receptacle 342 after use. In some configurations, the user may simply grab the used penetrating member, pull it out of the cartridge, and deposit it into a receptacle. In a still further embodiment, a used penetrating member may be ejected from the cartridge during the process of loading a new penetrating member. The used penetrating member is ejected out into a receptacle 346.

Referring now to Figure 22, another embodiment of the present invention will now be described. Figure 22 shows a method for use with a penetrating member driver 350 which is brought together with a multiple penetrating member cartridge 352 or single cartridge 354 only during use. After use, the cartridge and driver are separated for ease of storage, sterility, or other reasons. As seen, the cartridge 352 may be inserted into slot 358. Although not limited to the following, the penetrating member driver may be any of those described herein or the applications incorporated by reference. The driver may also

be any of those described in commonly assigned, copending U.S. Patent Application Ser. No. _______ (Attorney Docket No. 38187-2663) filed __________, fully incorporated herein by reference. In one embodiment, a case may be provided to store both the driver and the cartridge, or just the driver, or just the cartridge.

Referring now to Figure 23, a plurality of the cartridges 352 are shown. Each may contain a penetrating member 360. These cartridge 352, in this embodiment, may be substantially equivalent to on cavity on the cartridge 242. The cartridge 352 may include an area that has sufficient interference fit to grip a penetrating member and it may have an elongate opening on one side, such as but not limited to top or bottom, to allow a penetrating member coupler to engage the penetrating member 360 therein. It should be understood, that in some embodiments, only proximal and distal end openings are provided.

Referring now to the embodiment shown in Figure 24, a plurality of cartridges 352 are coupled together by some layer of material 362. They may use a sterility barrier to couple them together. In another embodiment, a mold plastic or polymer may be used to couple the cartridge 352 together. The cartridges maybe designed to allow access from the top as indicated by arrow 364 or from the bottom 366.

Figure 25 shows a still further embodiment where a distal portion 370 is not covered by the sheet 362. In this embodiment, this is where a punch would come down and punch down material covering the front.

Figure 26 shows an embodiment where the cartridges may be coupled into a configuration as shown.

Referring now to Figures 27 and 28, embodiments of cartridges 352 coupled together is shown used with rollers 380 and a support surface 382 over the active region. A penetrating member coupler 384 may be used to engage penetrating members inside the cartridge 352. The cartridges may be rotated as indicated by arrows 386 to bring cartridges into alignment with the coupler 384.

Figure 28 shows a similar embodiment where the roller 388 has teeth 390 to engage spaces between the cartridges 352. The embodiment in Figure 28 allows the coupler 384 to pierce through the material 362 to engage the penetrating member therein. In one configuration, the punch and opening of the sterility barrier is very similar to those techniques used for cartridge 242.

Figure 29 shows a still further embodiment where the cartridges 352 are in an elongate strung out configuration that may be layer on top of each other or otherwise configured to efficiently store the tape of cartridges 352. The embodiment of Figure 29 may include a cutter at the position indicated by dotted line 392 where the material 362 is cut and the used cartridge 352 may be discarded. The cutter (not shown) may any of those known to those of skill in the art.

Referring now to Figure 30, a still further embodiment is shown where a penetrating member driver 400 may be coupled to cartridge 402 containing a plurality of penetrating members. The cartridge 402 may snap on the holder 404 and be held in place similar to that technique used by amaray or cases used to DVDs or CDs. A penetrating member 406 may be included.

Figure 31 shows a still further embodiment where disc 420 holding the penetrating members are contained inside a housing 422. The housing 422 may be coupled to a penetrating member driver 424. Any of the drivers disclosed herein may be used for the driver 424. Again, the configurations here may teach a method of use where the penetrating members and drivers are brought together only when the sampling is about to occur.

Referring now to Figures 32 through 37 show embodiments of cartridges for use with device 240. Figure 32 shows a full circular cartridge 440 with a reduced number of cavities 442 spaced apart on the cartridge. Figure 33 shows a single cartridge 450 holding a single penetrating member. Figure 34 shows a cartridge 460 having two wedge configuration. Figure 35 shows a cartridge 462 having a single cavity per finger 463. Of course in other embodiments, there may be more than one cavity in each finger. The entire cartridge may also be a partial circular configuration (half-circular, quarter circle, wedge, etc...). Figure 36 shows an embodiment of a cartridge 470 with a half circular or ¼ circular or wedge configuration. Figure 37 shows a cartridge 480 that may have portions, such as but not limited to quarters, thirds, or other fractions, on it that are colored or otherwise marked to show, as a nonlimiting example, number of penetrating members remain or the type of analyte test held therein.

While the invention has been described and illustrated with reference to certain particular embodiments thereof, those skilled in the art will appreciate that various adaptations, changes, modifications, substitutions, deletions, or additions of procedures and protocols may be made without departing from the spirit and scope of the invention.

For example, with any of the above embodiments, the location of the penetrating member drive device may be varied, relative to the penetrating members or the cartridge. With any of the above embodiments, the penetrating member tips may be uncovered during actuation (i.e. penetrating members do not pierce the penetrating member enclosure or protective foil during launch). With any of the above embodiments, the penetrating members may be a bare penetrating member during launch. With any of the above embodiments, the penetrating members may be bare penetrating members prior to launch as this may allow for significantly tighter densities of penetrating members. In some embodiments, the penetrating members may be bent, curved, textured, shaped, or otherwise treated at a proximal end or area to facilitate handling by an actuator. The penetrating member may be configured to have a notch or groove to facilitate coupling to a gripper. The notch or groove may be formed along an elongate portion of the penetrating member. With any of the above embodiments, the cavity may be on the bottom or the top of the cartridge, with the gripper on the other side. In some embodiments, analyte detecting members may be printed on the top, bottom, or side of the cavities. The front end of the cartridge maybe in contact with a user during lancing. The same driver may be used for advancing and retraction of the penetrating member. The penetrating member may have a diameters and length suitable for obtaining the blood volumes described herein. The penetrating member driver may also be in substantially the same plane as the cartridge. The driver may use a through hole or other opening to engage a proximal end of a penetrating member to actuate the penetrating member along a path into and out of the tissue. The embodiments herein are adapted for use with lancing devices described in U.S. Patent Applications Ser. No. ________ Attorney Docket No. 38187-2551US and 38187-2606.

Expected variations or differences in the results are contemplated in accordance with the objects and practices of the present invention. It is intended, therefore, that the invention be defined by the scope of the claims which follow and that such claims be interpreted as broadly as is reasonable.

WHAT IS CLAIMED IS:

1. A method of body fluid sampling comprising:

moving a penetrating member at conforming to a selectable velocity profile or motion waveform;

using a pie-shaped cartridge for housing said penetrating member;

piercing a storage area having a sensing area;

piercing another storage area having an enzyme area separate from the sensing area prior to piercing;

causing fluid to first flow to the enzyme area and then to the sensing area.

2. The device of claim 1 further comprising storing said enzyme area in an inert environment different from an environment for the sensing area.

3. A device for body fluid sampling usable with a cartridge housing a plurality of penetrating members, the device comprising:

a housing;

a penetrating member driver coupled to said housing and for use with said cartridge;

a processor for controlling said penetrating member driver to move at least one of said penetrating members at velocities which conform with a selectable velocity profile;

a storage area having a sensing area;

another storage area having an enzyme area separate from the sensing area prior to piercing;

wherein said penetrating member pierces opens both storage areas upon member actuation and causing body fluid to first flow to the enzyme area and then to the sensing area.

## ABSTRACT OF THE DISCLOSURE

A method of body fluid sampling is provided. The method comprises moving a penetrating member at conforming to a selectable velocity profile or motion waveform; piercing a storage area having a sensing area; piercing another storage area having an enzyme area separate from the sensing area prior to piercing; and causing fluid to first flow to the enzyme area and then to the sensing area. The method may further comprise storing said enzyme area in an inert environment different from an environment for the sensing area. Various cartridges holding penetrating members for use with the present invention are shown.

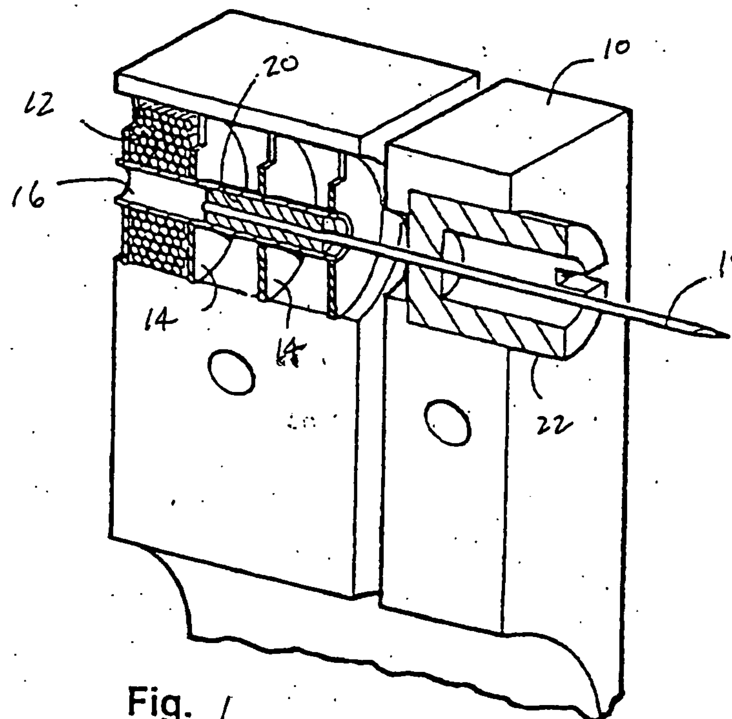



Fig. 1

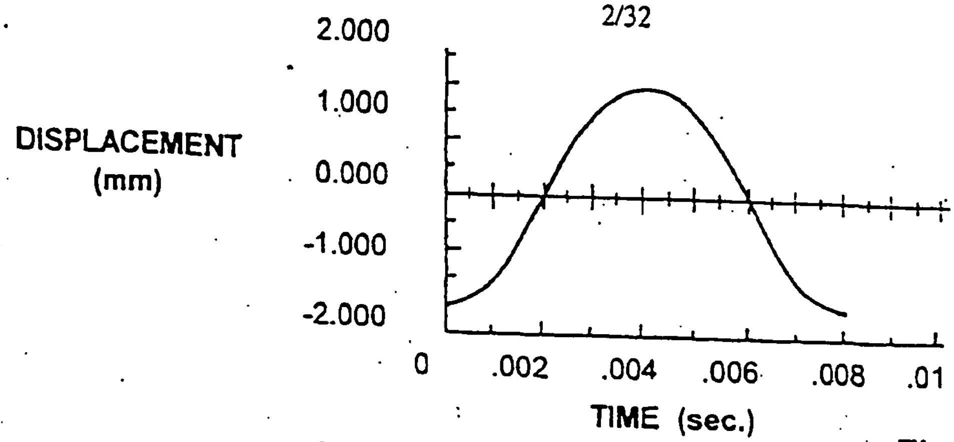



Fig. 2A

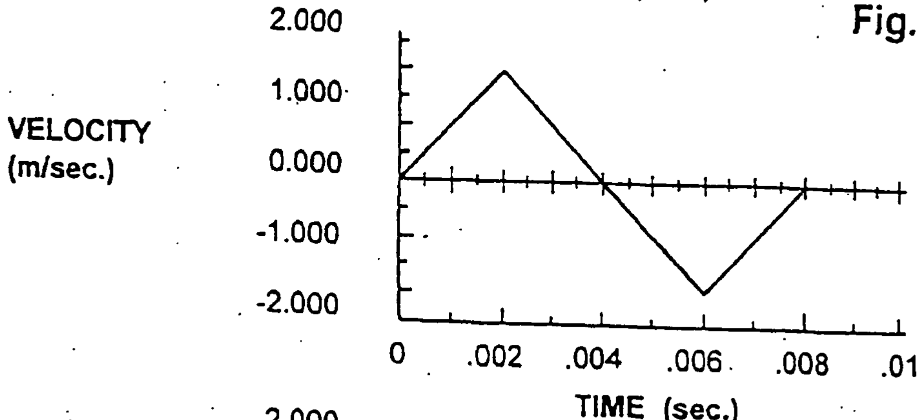



Fig. 2B

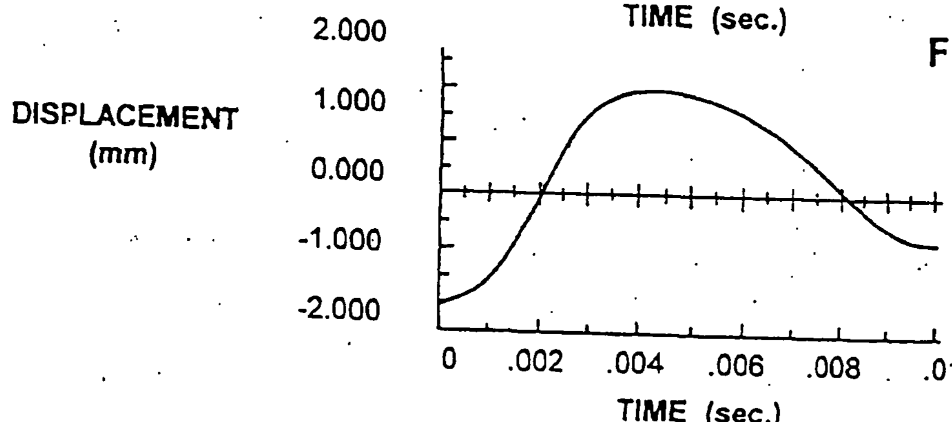



Fig. 2C

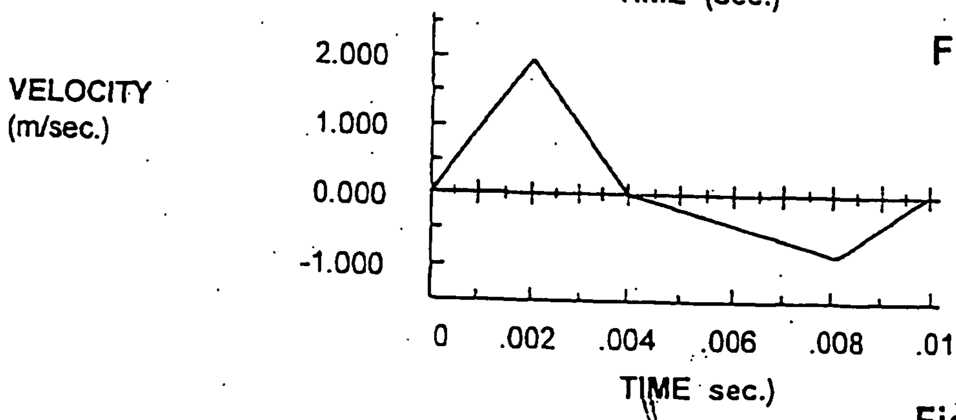



Fig. 2D

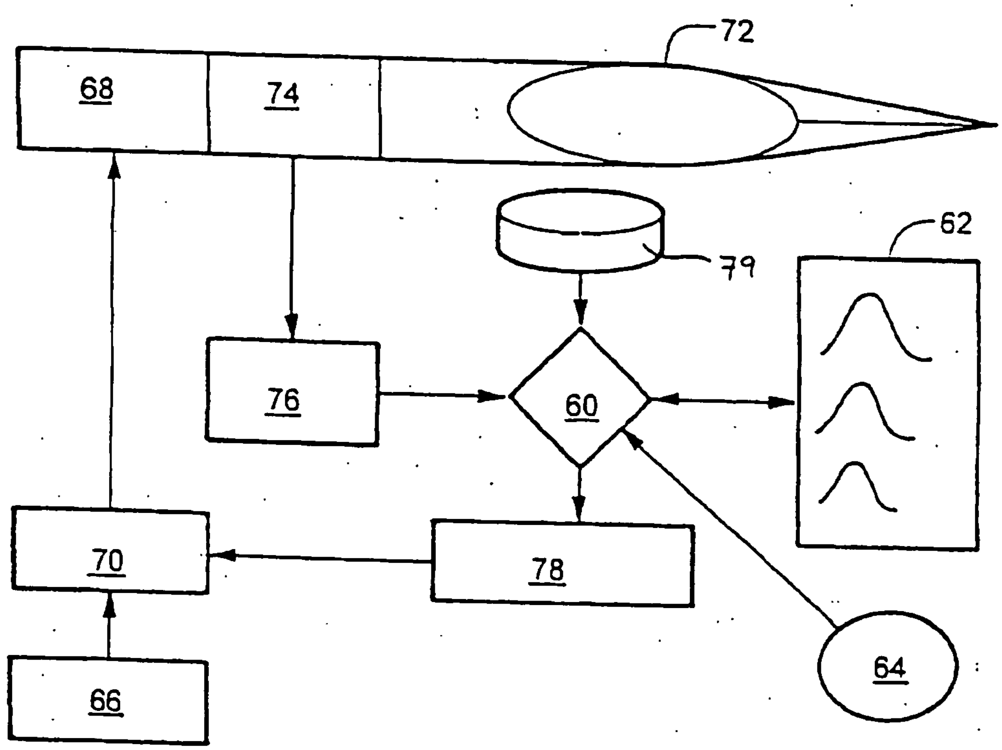
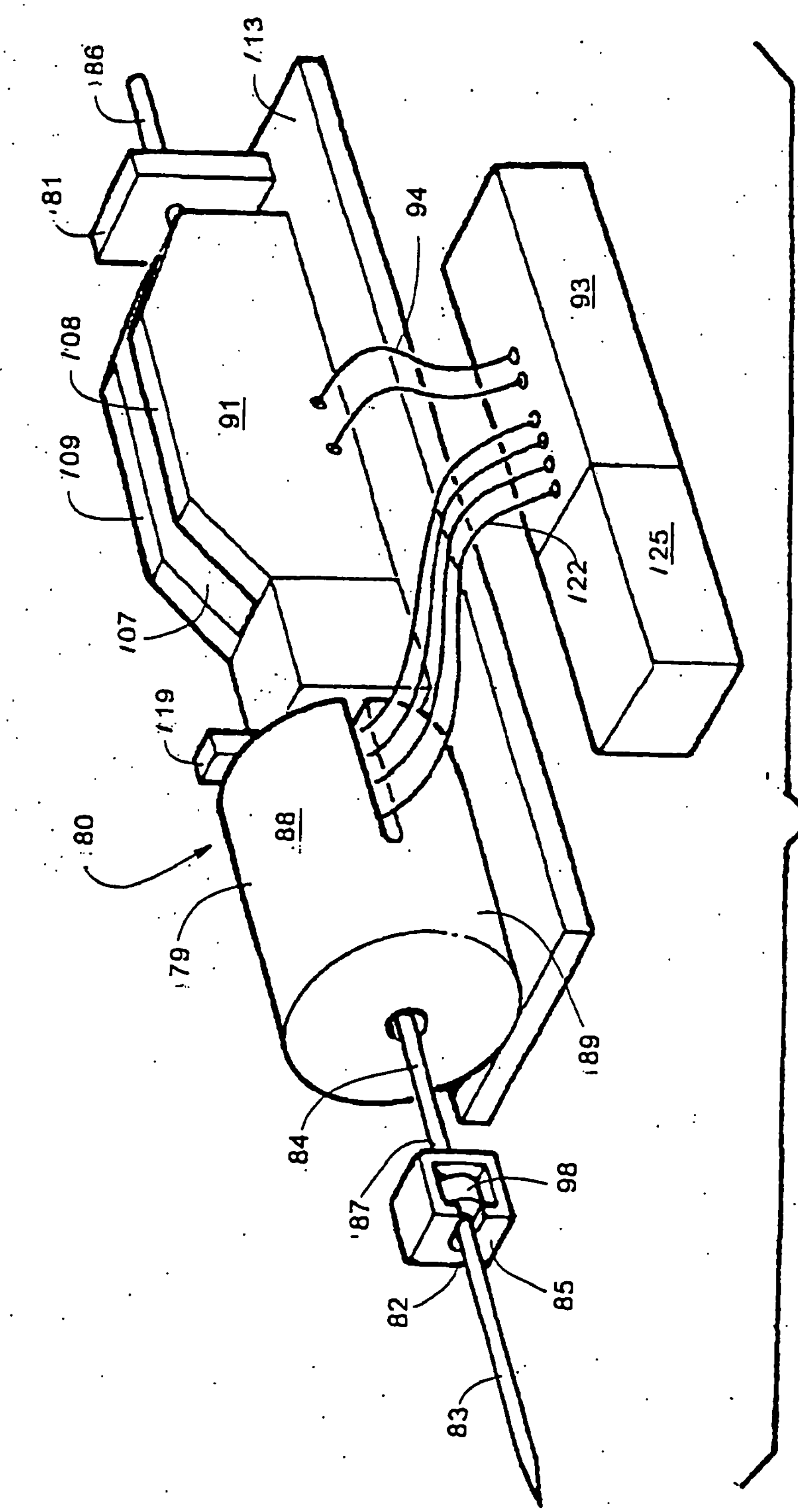



Fig. 3



86
113
81
94
93
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122
125
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119
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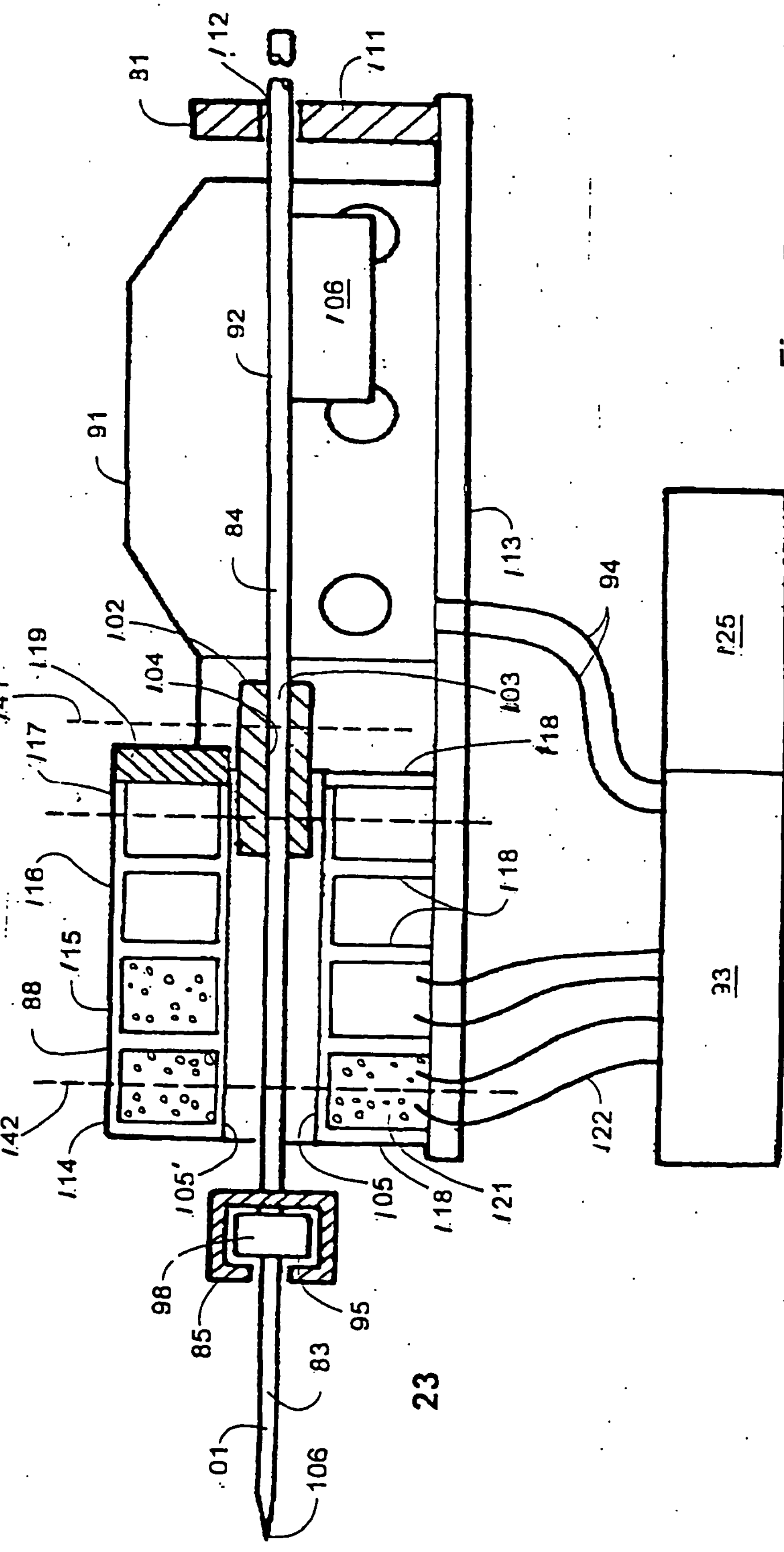
85
83


Fig. 4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114
105'
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122
33
98
85
95
83
01
106
23

Fig. 5

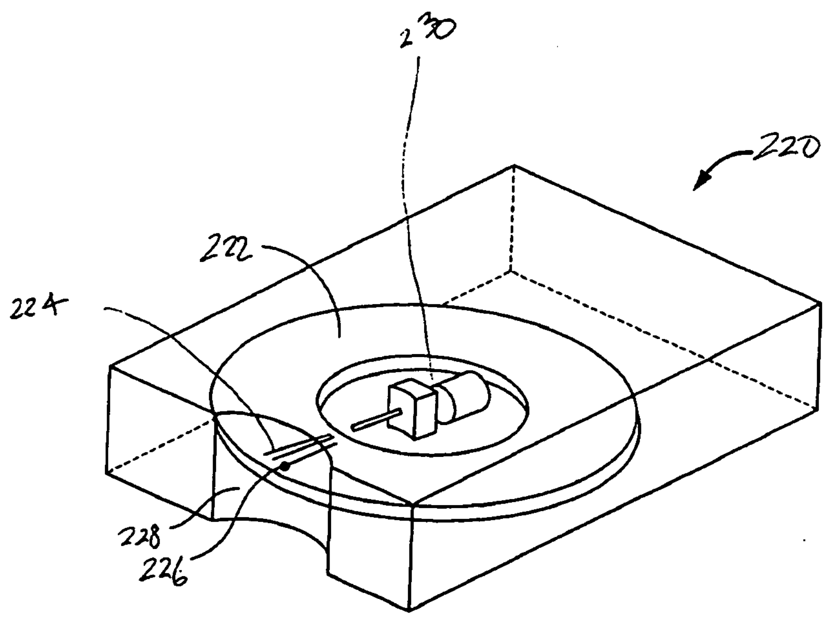



FIG_6

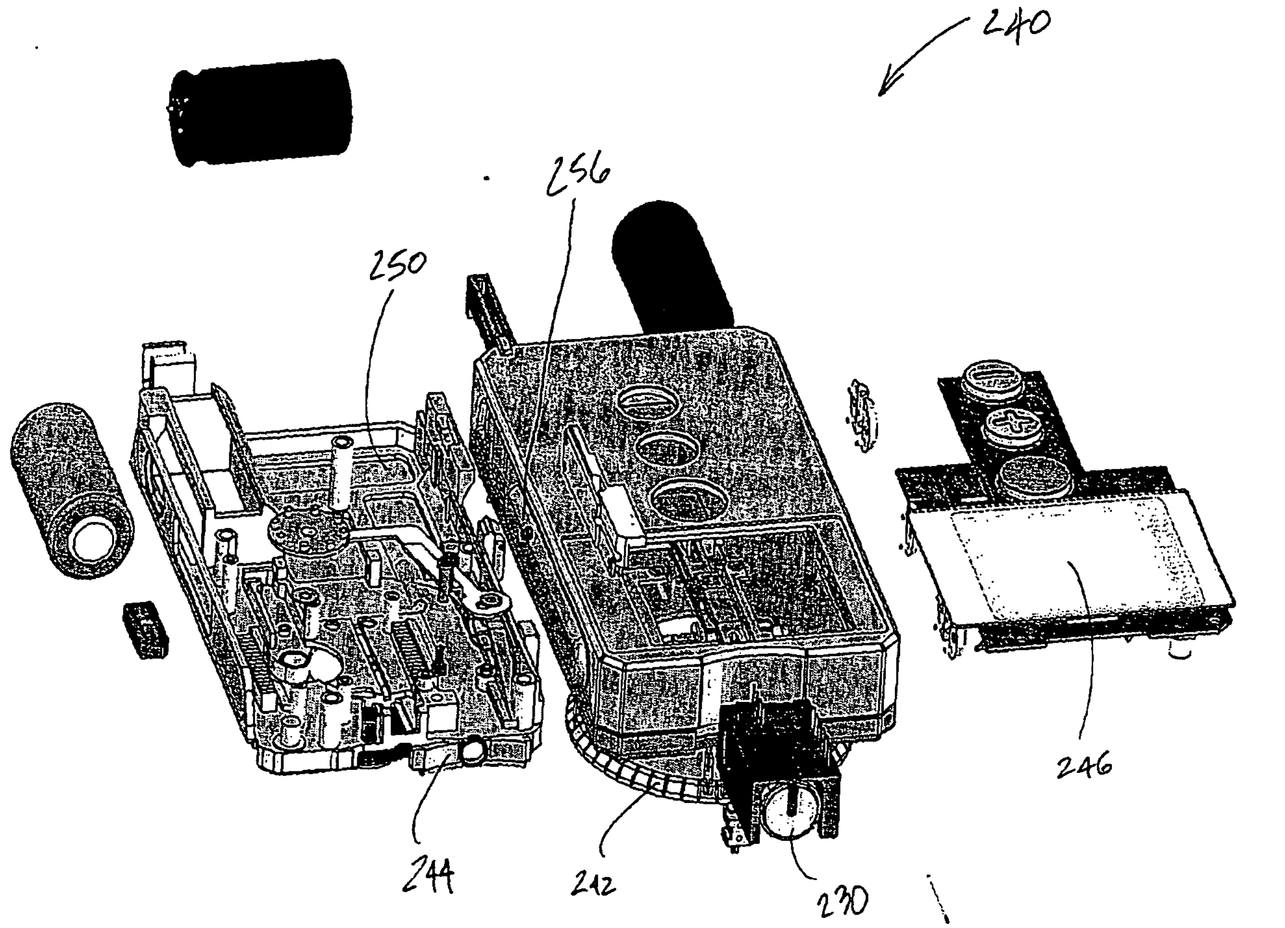



FIG_7

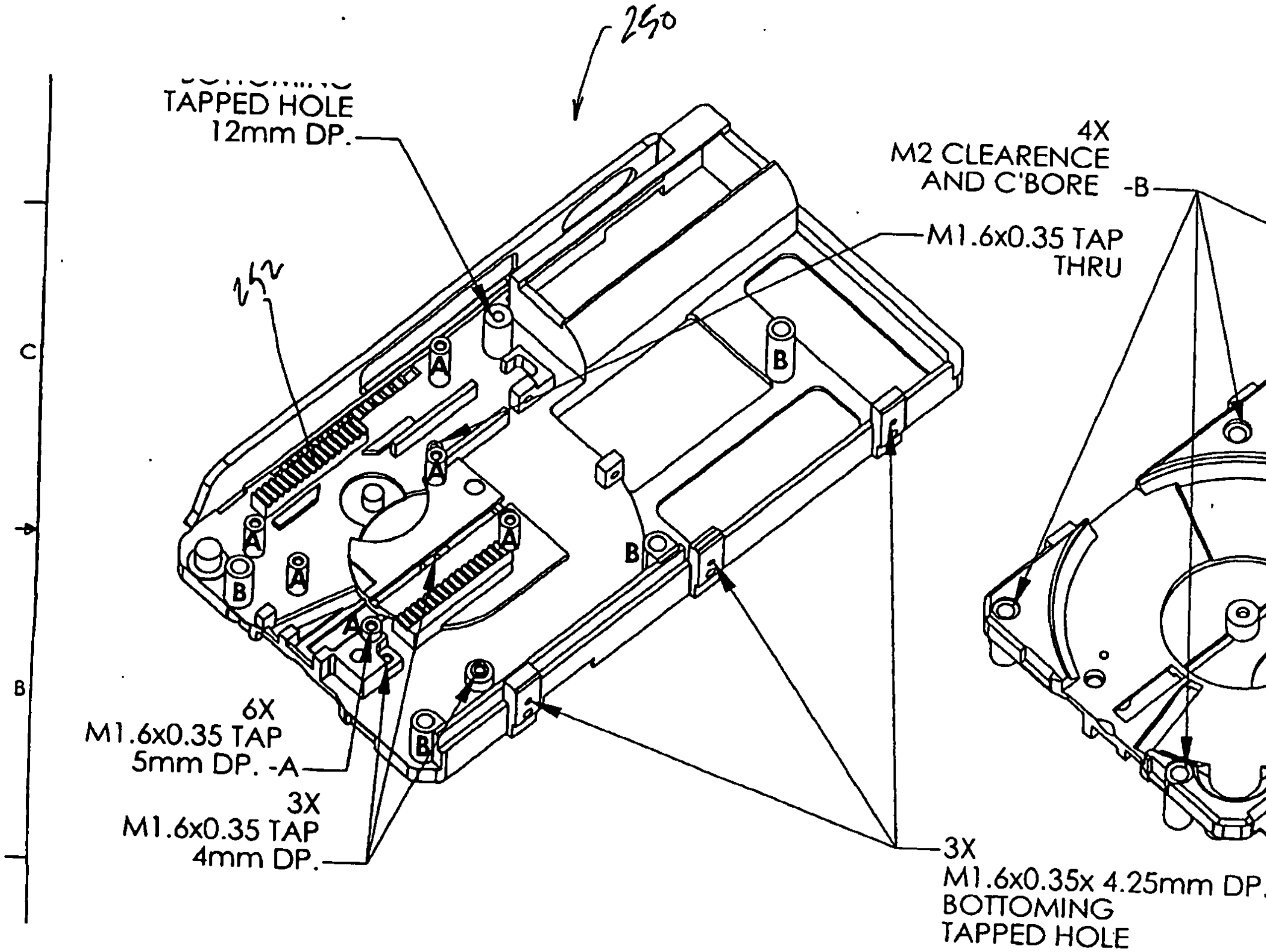

250
TAPPED HOLE
12mm DP.
252
M1.6x0.35 TAP
THRU
6X
M1.6x0.35 TAP
5mm DP. -A
3X
M1.6x0.35 TAP
4mm DP.
3X
M1.6x0.35x 4.25mm DP.
BOTTOMING
TAPPED HOLE
C
B

FIG_8

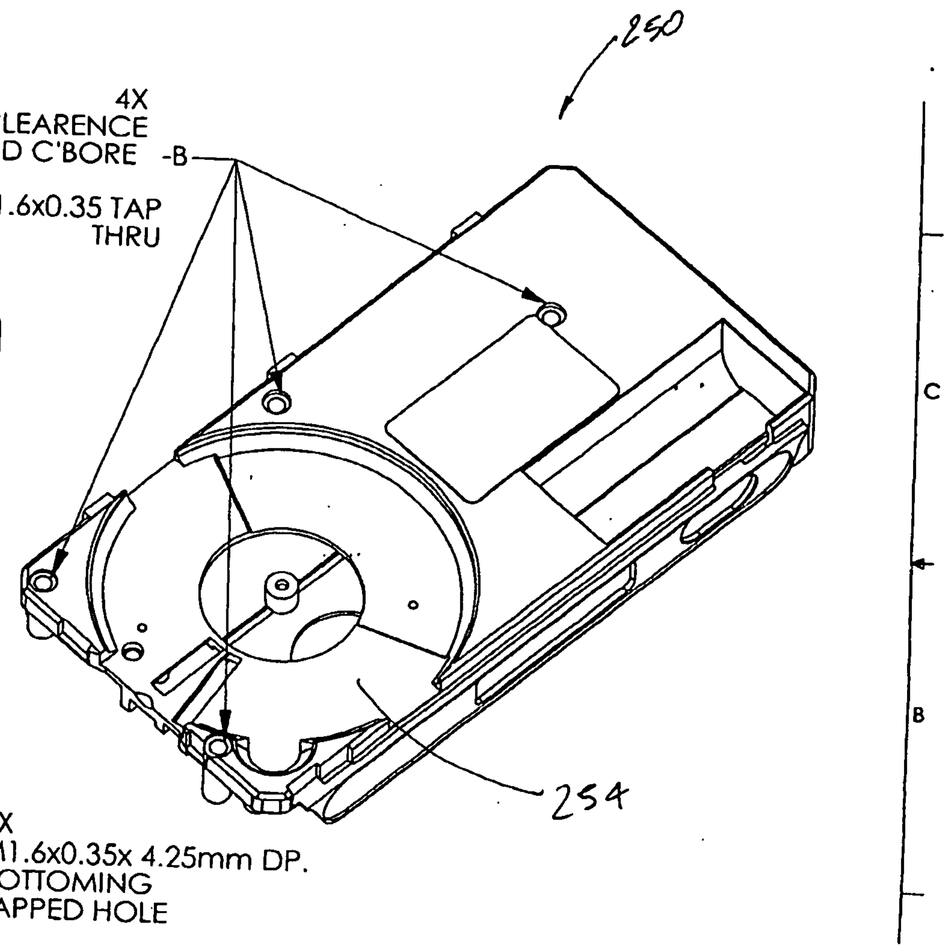
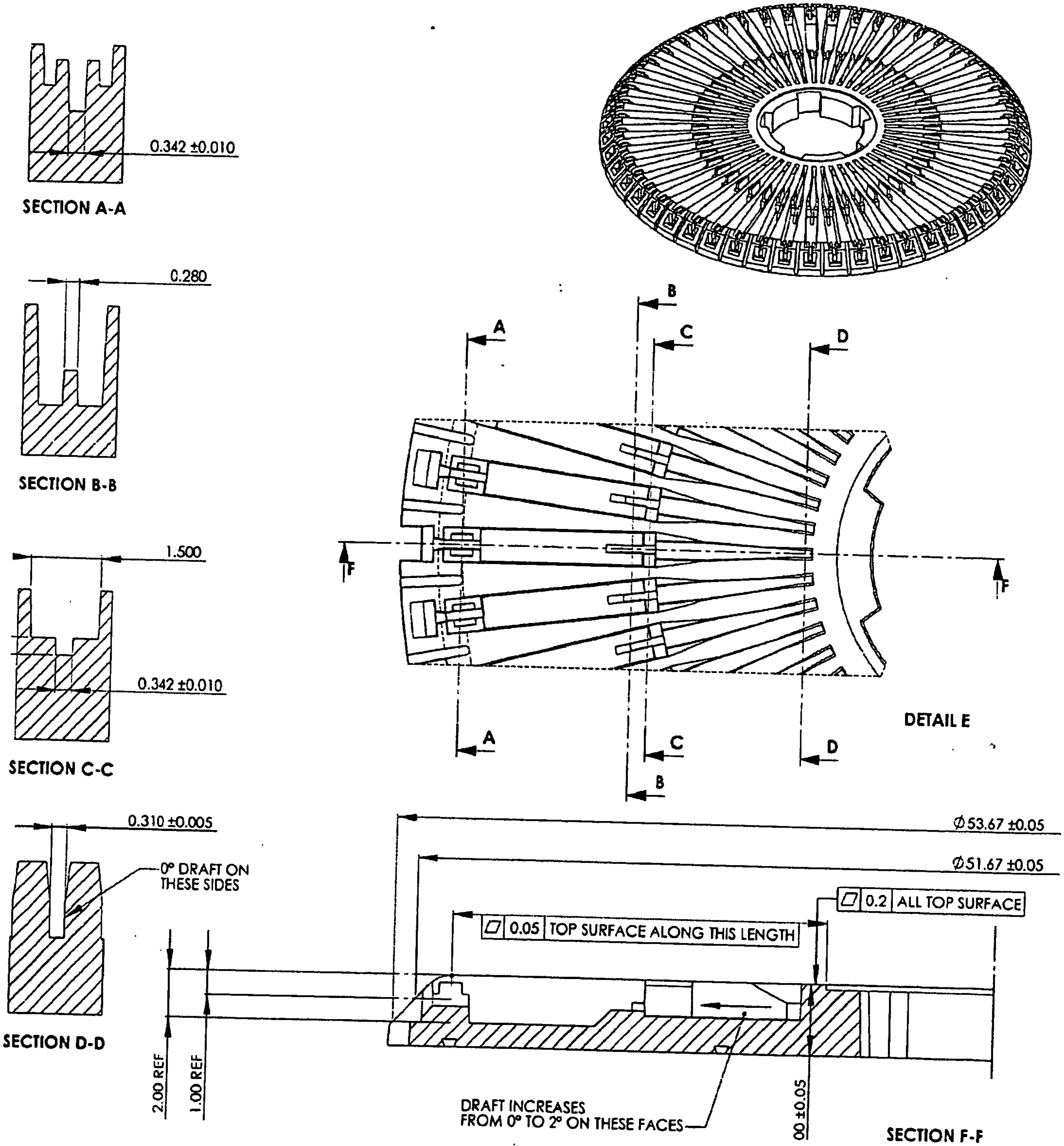

250
4X
M2 CLEARENCE
AND C'BORE -B
254
C
B

FIG_9



0.342 ±0.010
SECTION A-A
0.280
SECTION B-B
1.500
0.342 ±0.010
SECTION C-C
0.310 ±0.005
0° DRAFT ON THESE SIDES
SECTION D-D
B
A
C
D
F
F
DETAIL E
A
C
D
B
⌀53.67 ±0.05
⌀51.67 ±0.05
0.2 ALL TOP SURFACE
0.05 TOP SURFACE ALONG THIS LENGTH
2.00 REF
1.00 REF
DRAFT INCREASES FROM 0° TO 2° ON THESE FACES
00 ±0.05
SECTION F-F


FIG - 10

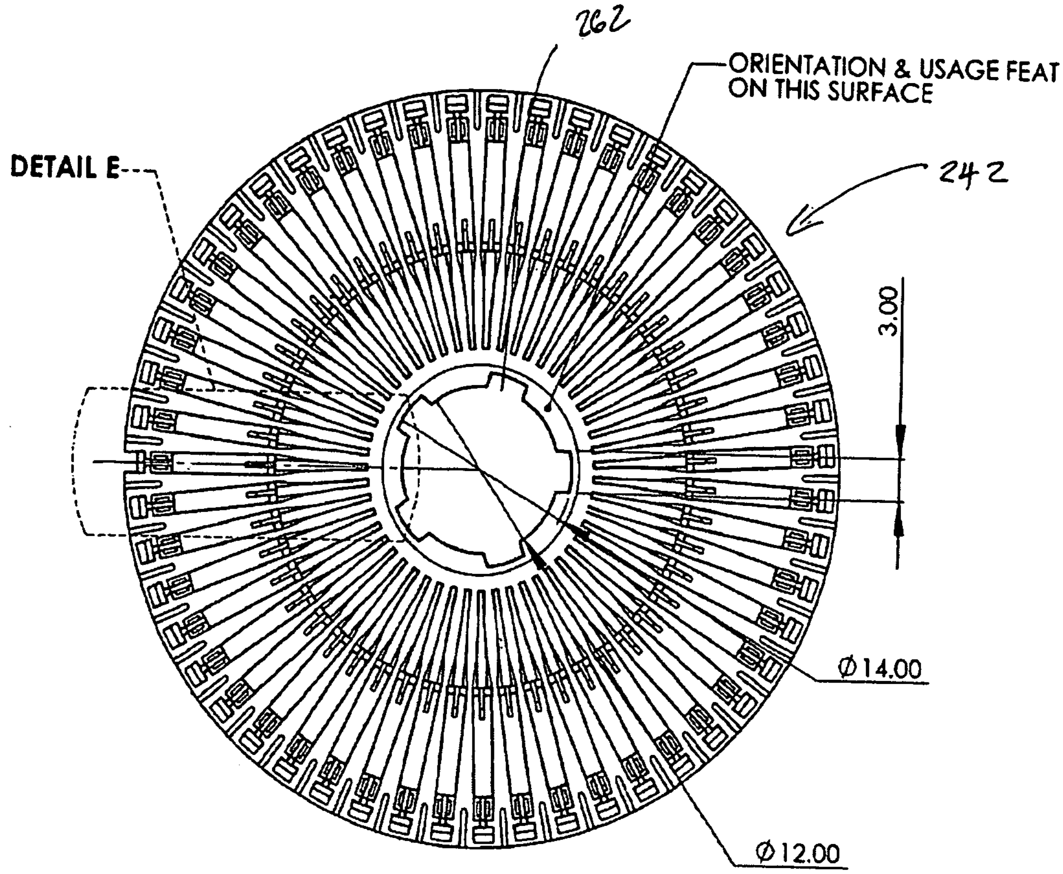
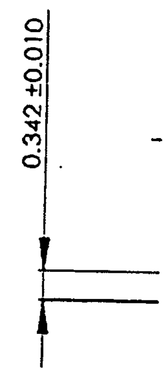



FIG_11

FIG_12



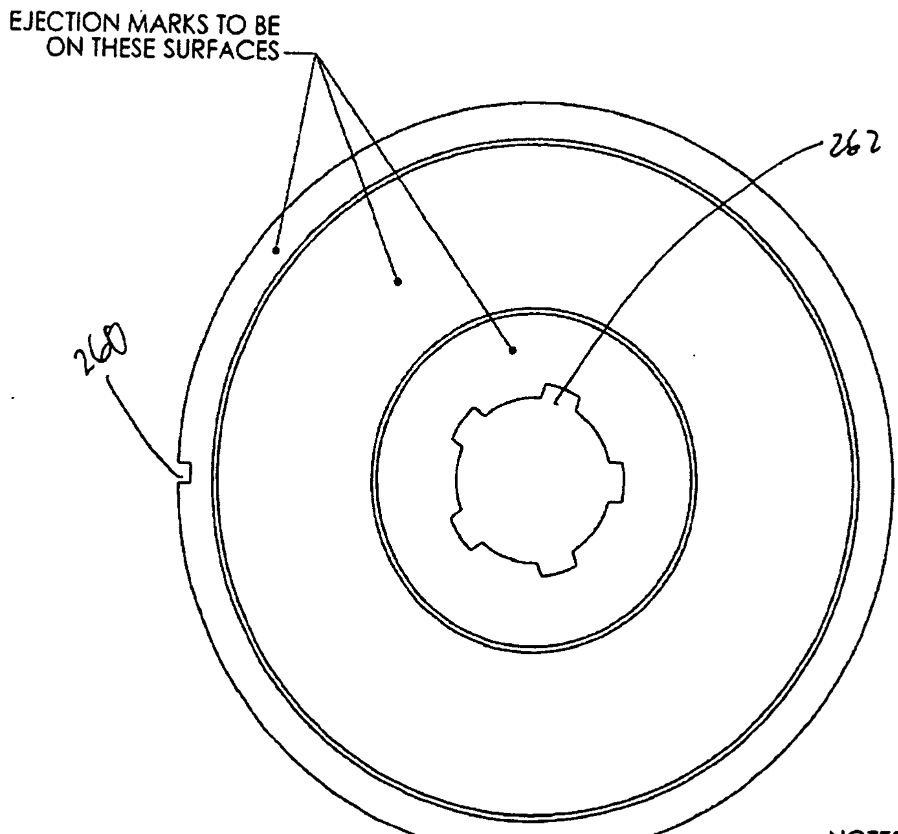




FIG_13

NOTES:-
1) 51 POCKETS IN TOTAL

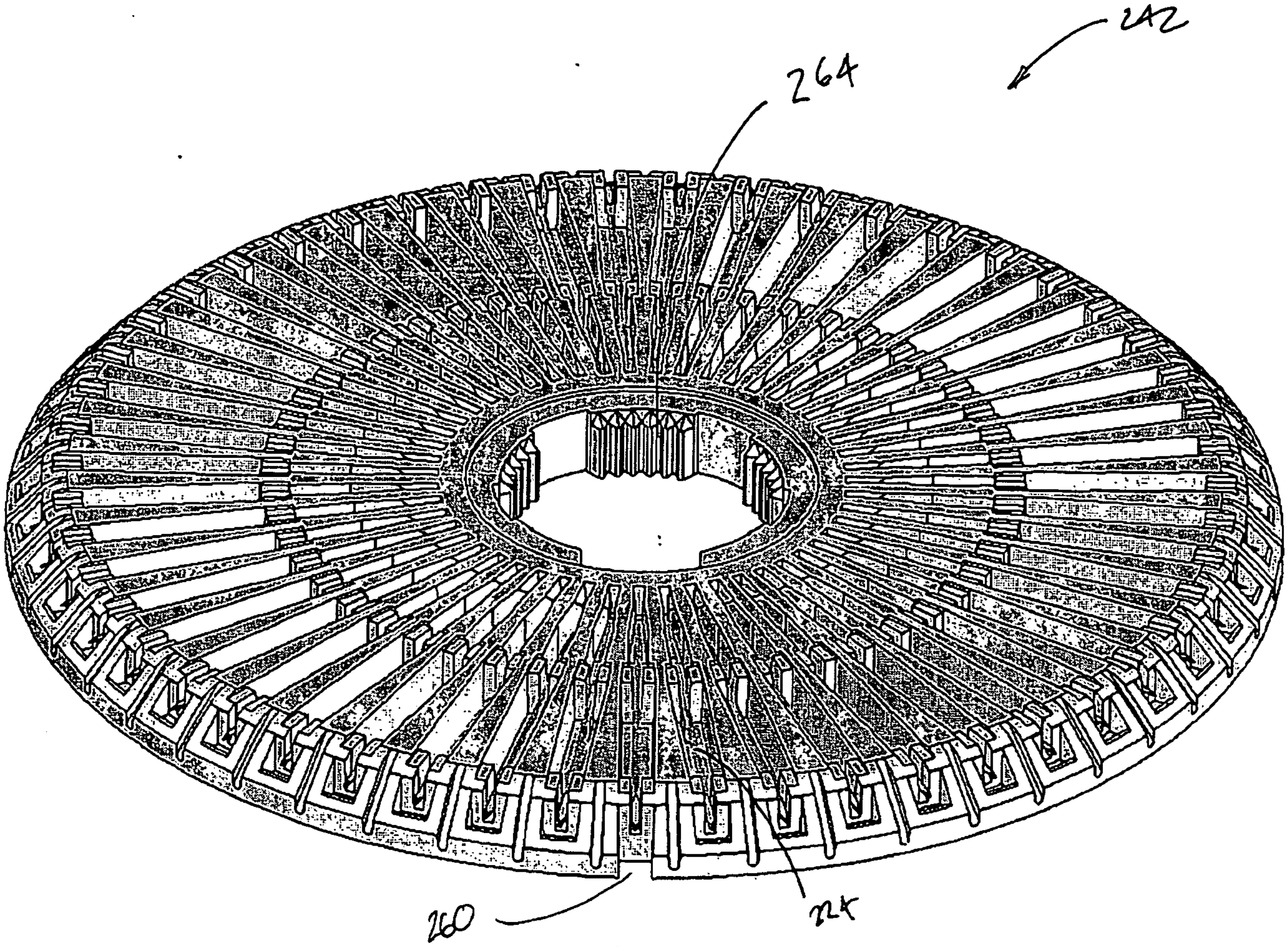



FIG_14

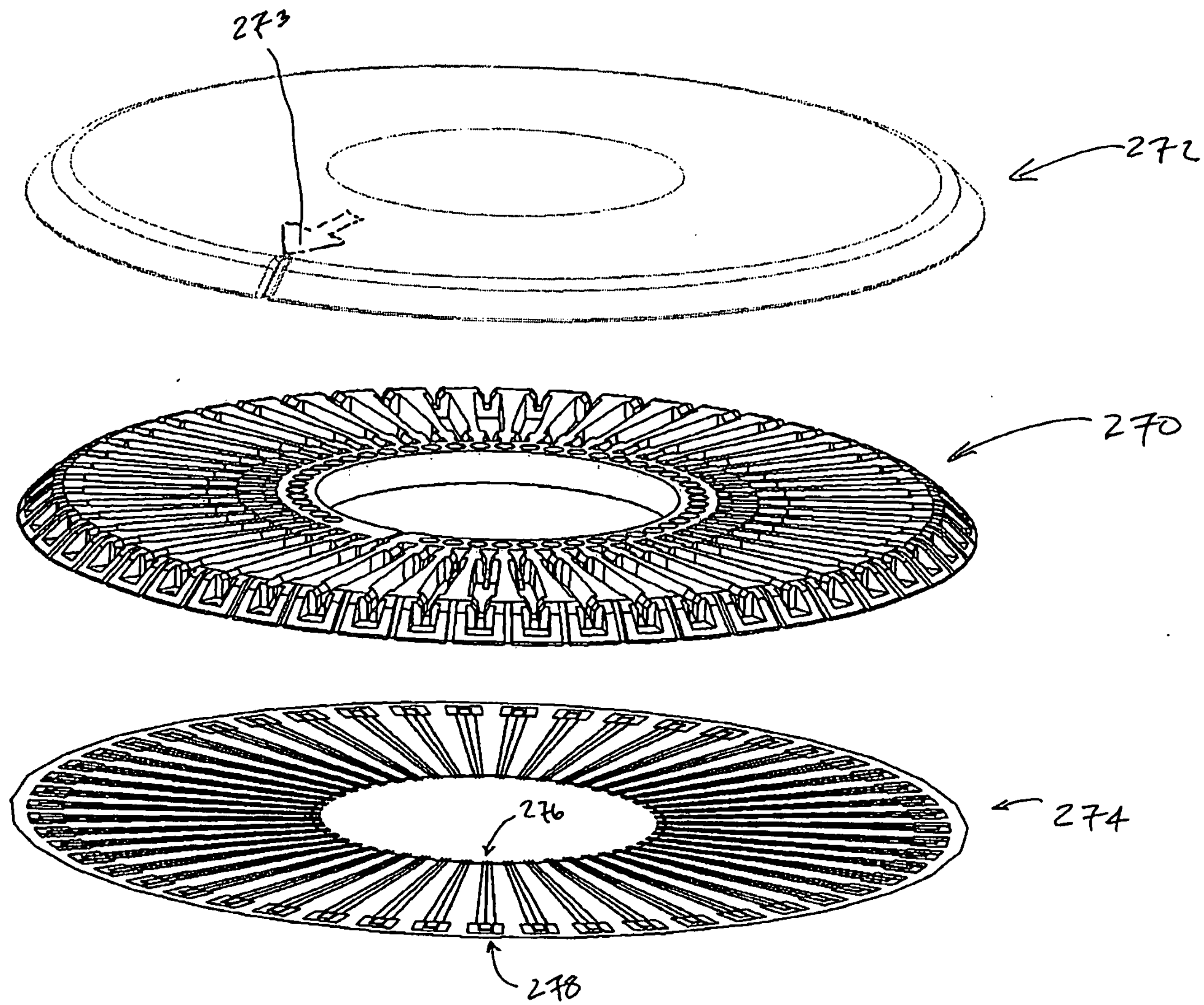



FIG_15

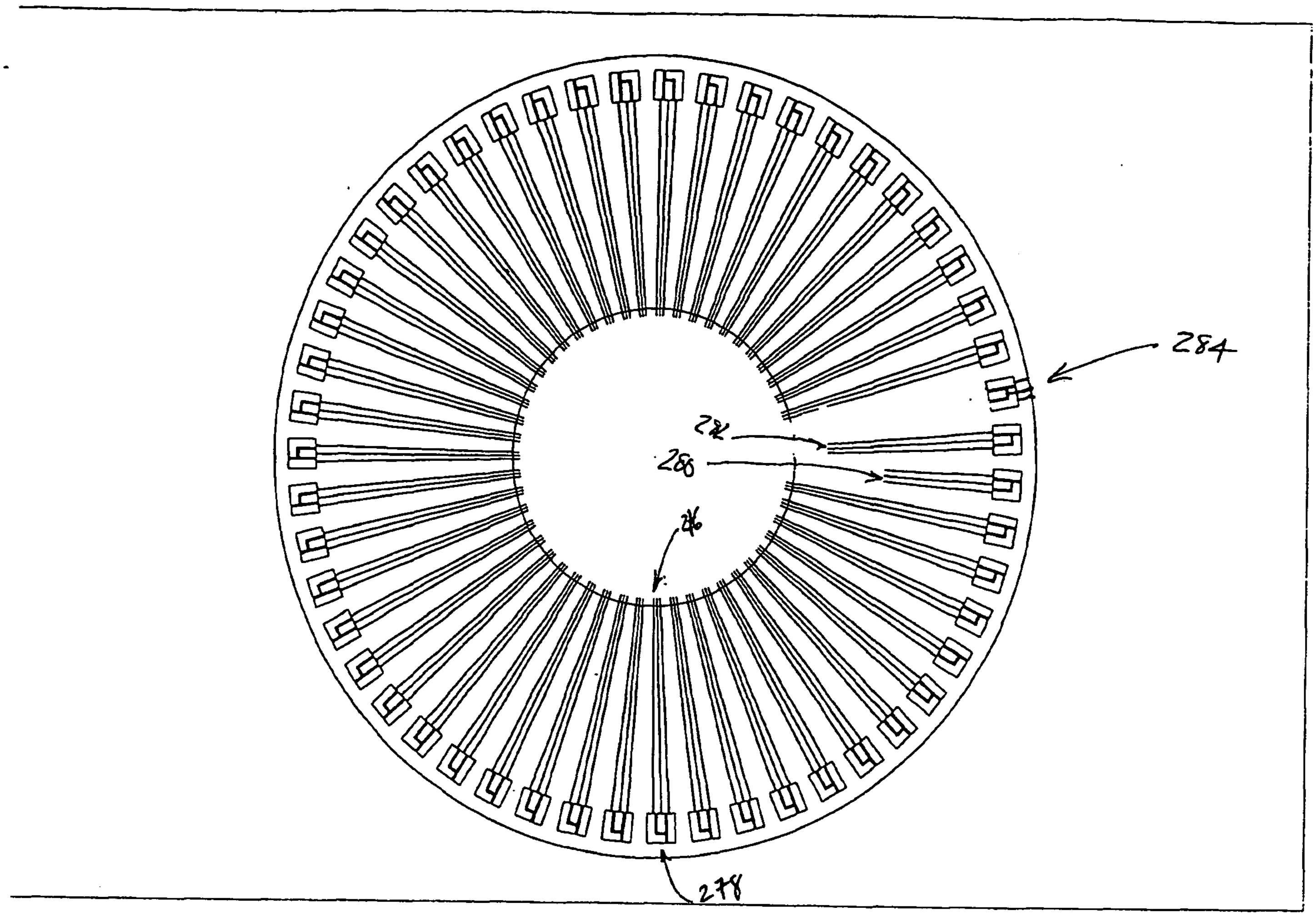



FIG_16

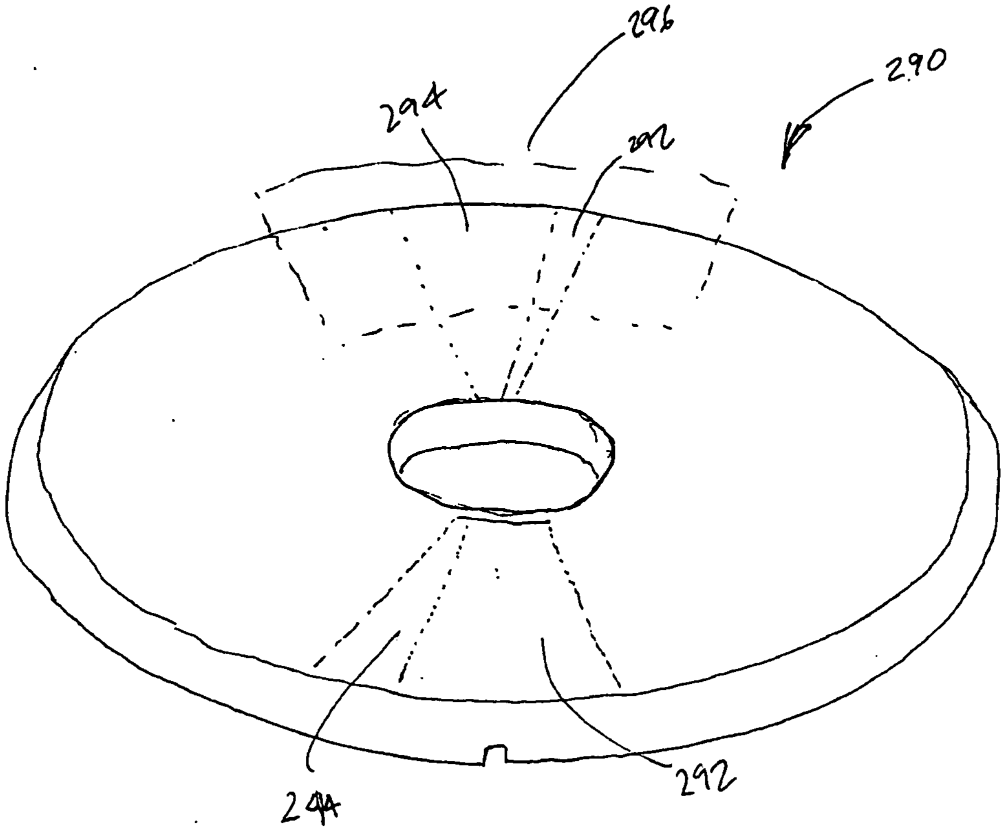



FIG-17

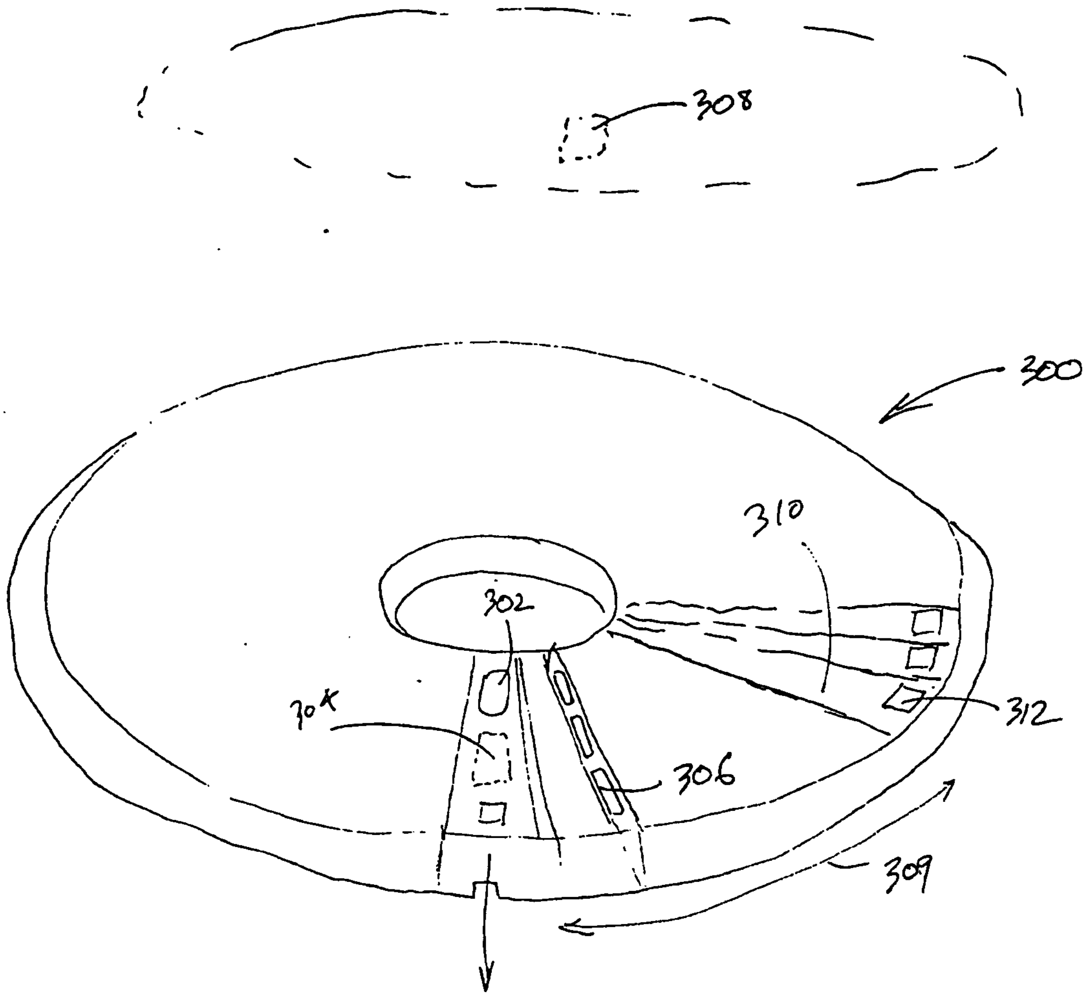



FIG_18

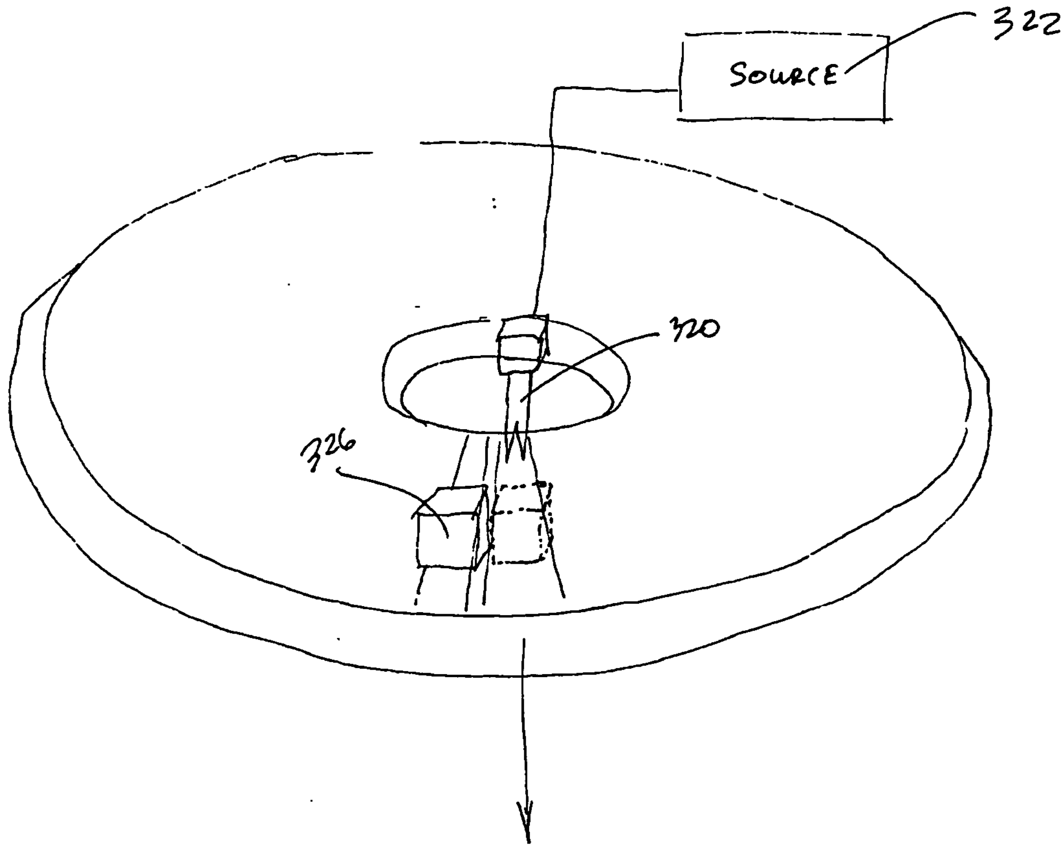



FIG-19

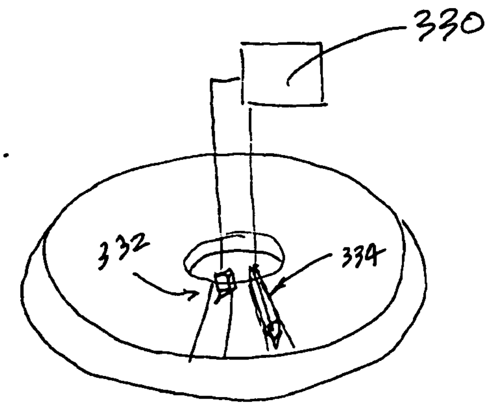



FIG-20

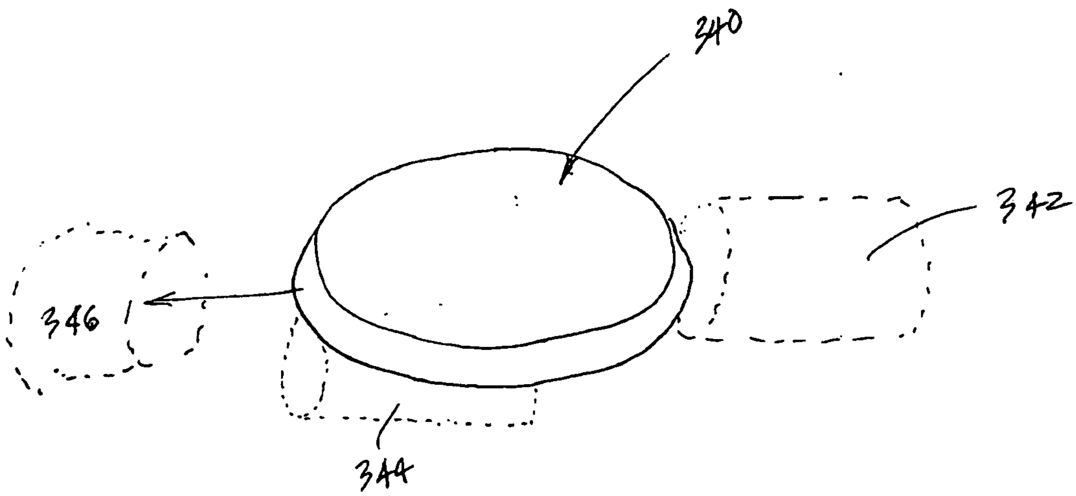



FIG - 21

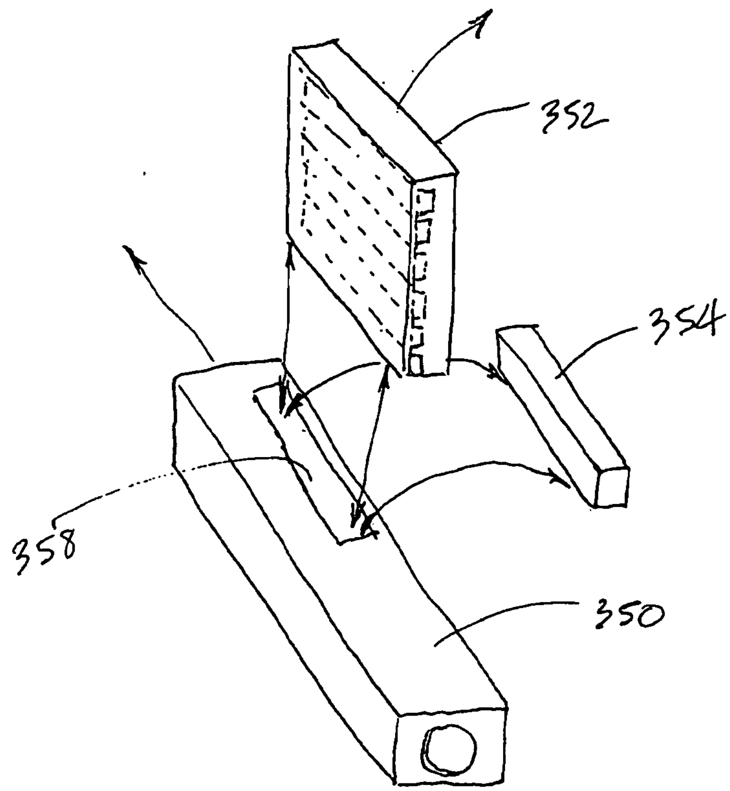



FIG-22

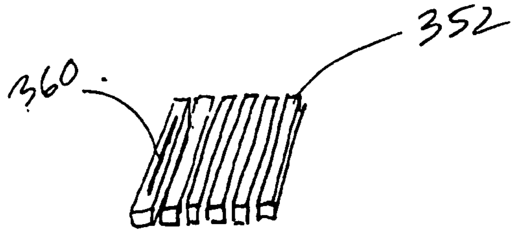



FIG_23

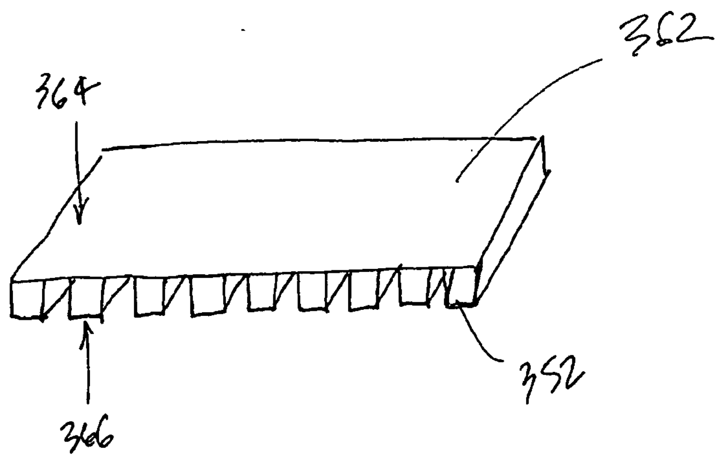



FIG_24

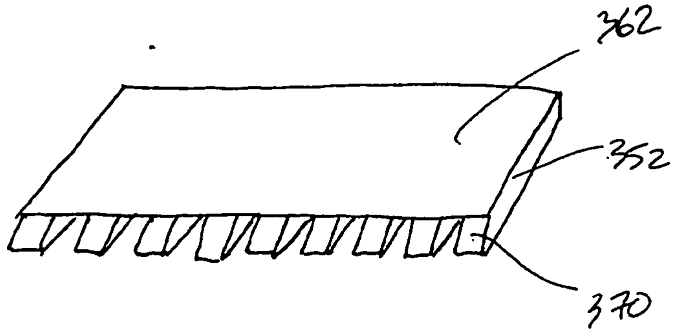



FIG. 25

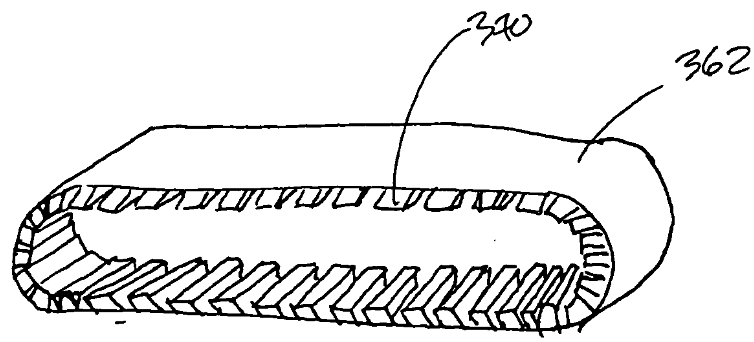



FIG. 26

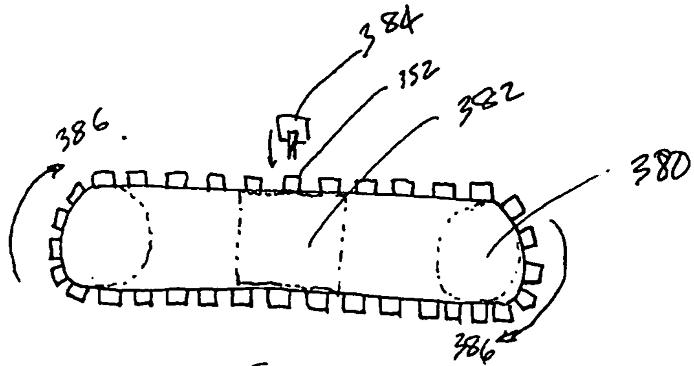


FIG-27

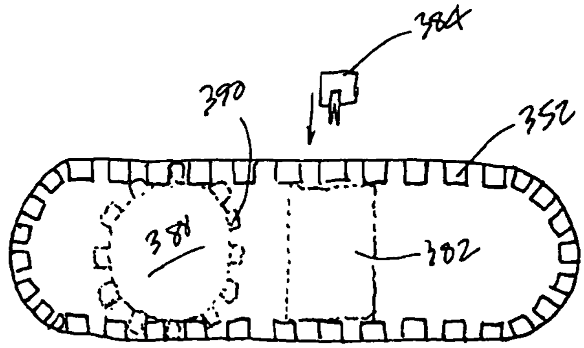


FIG-28

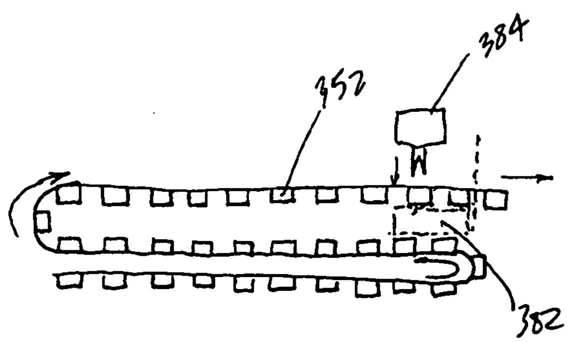


FIG-29

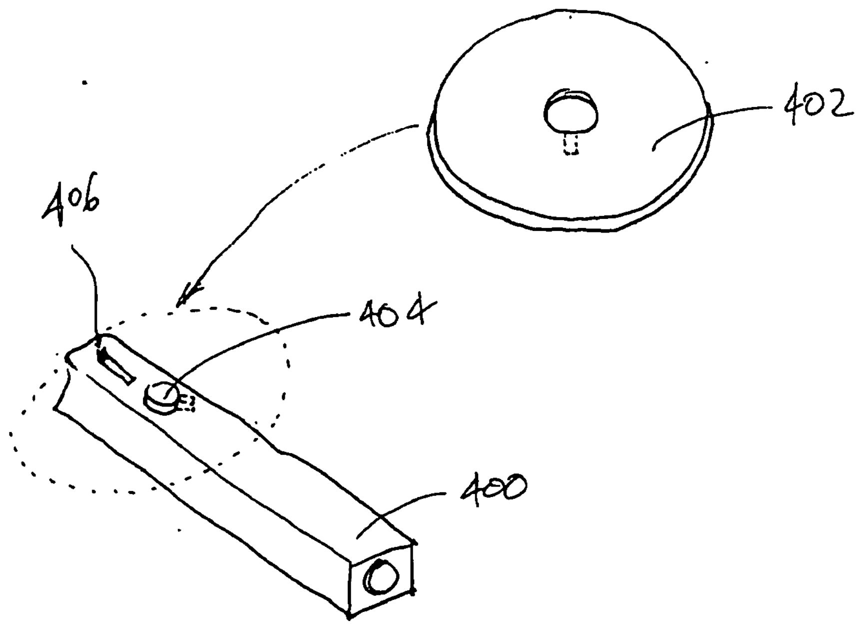



FIG_30

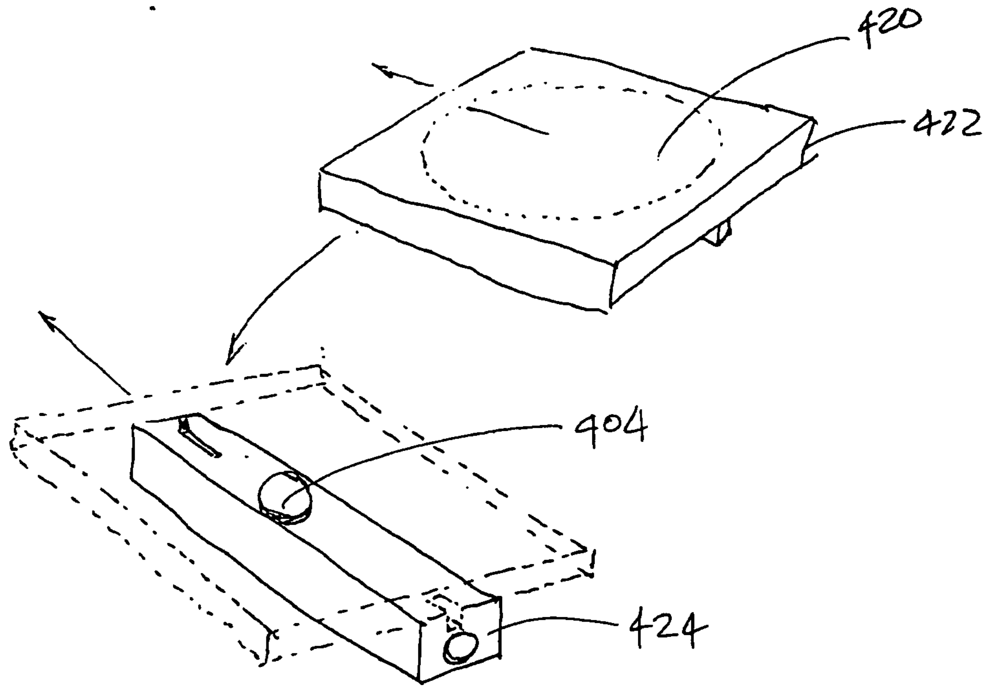



FIG_31

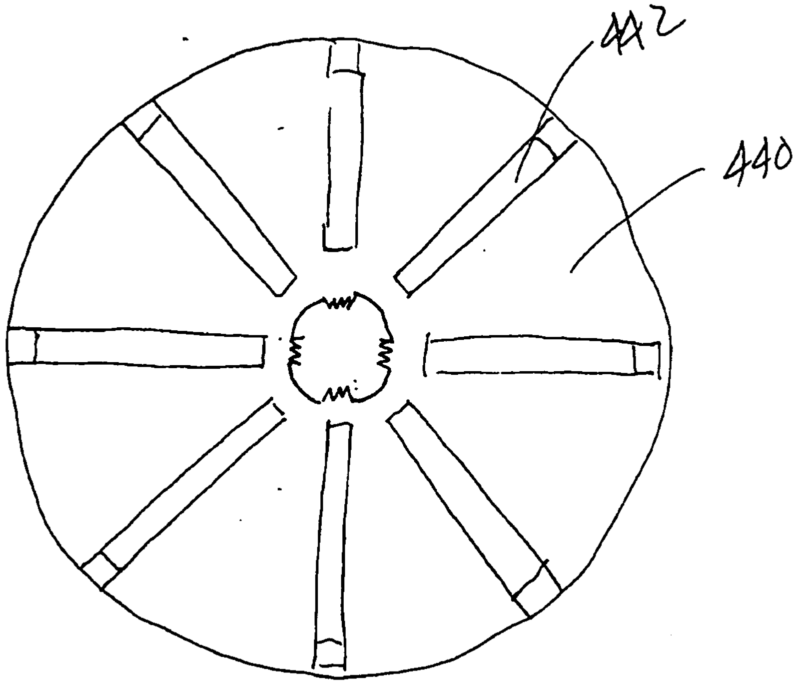



FIG-32

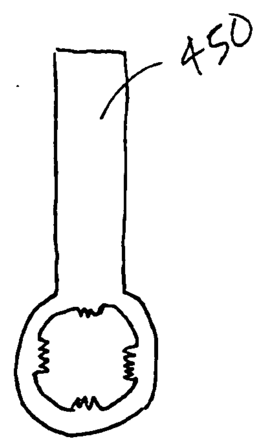



FIG-33

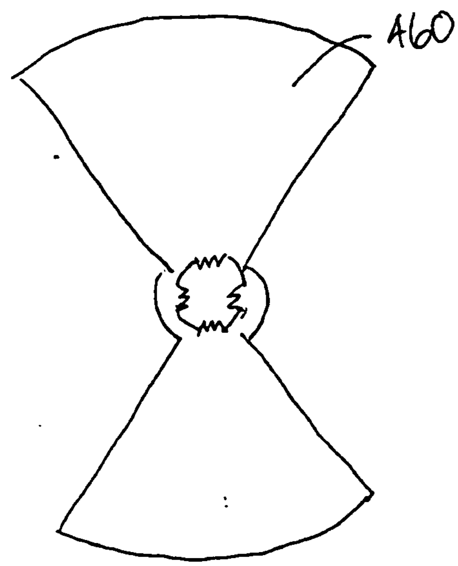



FIG_34

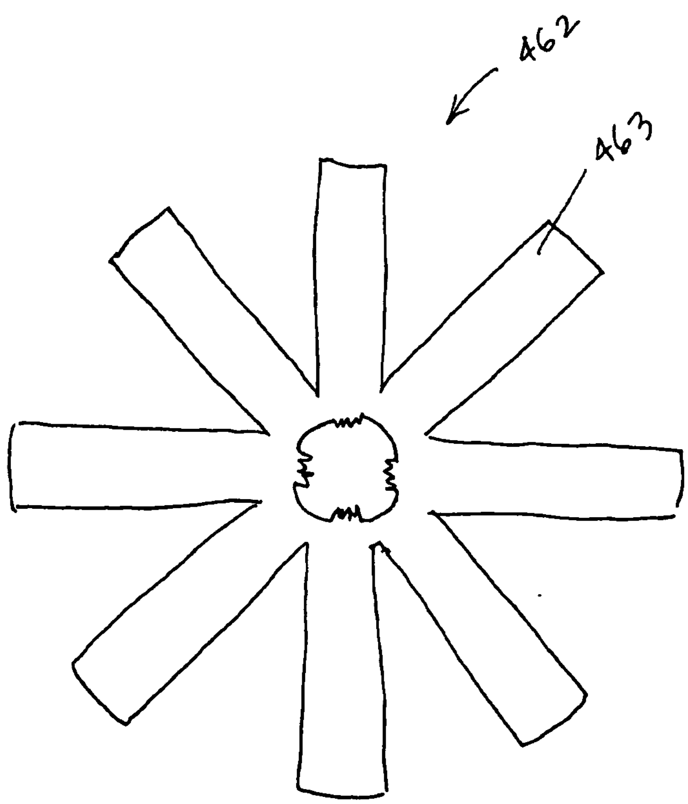



FIG_35

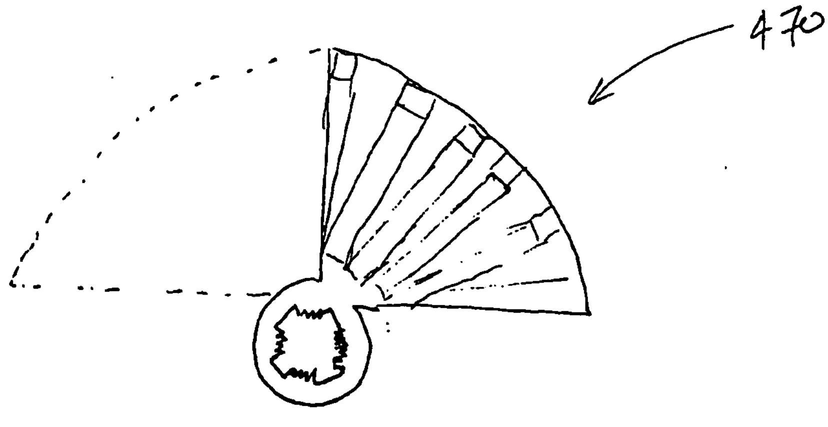



FIG_36

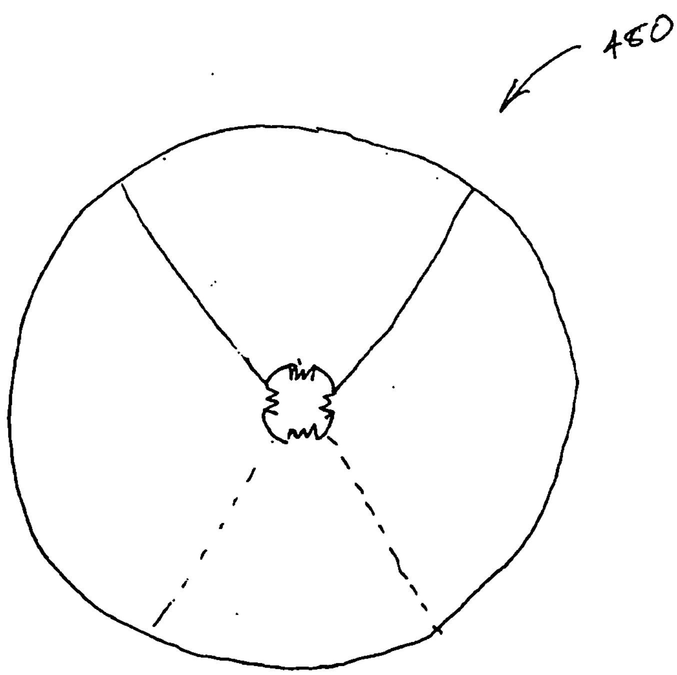



FIG_37

**Progress summary - against key lancet handling steps**

## Areas under investigation

| | |
|---|---|
| 4. Withdraw lancet or push lancet through storage medium<br>- further sequence steps are based on the assumption that we withdraw the lancet | - We have put a lot of effort into understanding the key geometrical constraints associated with the lancet and engine travel<br>- A spreadsheet showing the motion required (for both withdrawn lancets and pushed-through lancets) is attached (memo C6887-M-003) |
| 5. Align with guide hole | - This is a very difficult requirement – we need to fully understand the need for a tight fit on the shroud<br>- We have explored a number of ways of achieving the alignment – one of those is shown in this presentation |
| 6. Enter guide hole without damaging lancet tip<br>- old debris must not damage lancet | - We have not actively investigated this requirement yet. At the last progress meeting Dirk indicated that Pelikan had some good ideas in this area. We will review those before launching our own investigation here to avoid duplication of effort |
| 7. Fire and retract without damage and without scraping guide<br>- must not jam<br>- must not scrape bacteria into patient<br>- must not pick up guide hole debris and take into patient | - As 6 above |
| 8. Dump lancet in waste store<br>- without scraping off fluids where we don't want them<br>- alignment / not jamming on entry | - We are considering this requirement as we continue to investigate the cassette design |
| 9. Release from chuck <u>after</u> retaining in waste store | - This aspect has been covered as part of section 3 (how the chuck picks up the lancet) |

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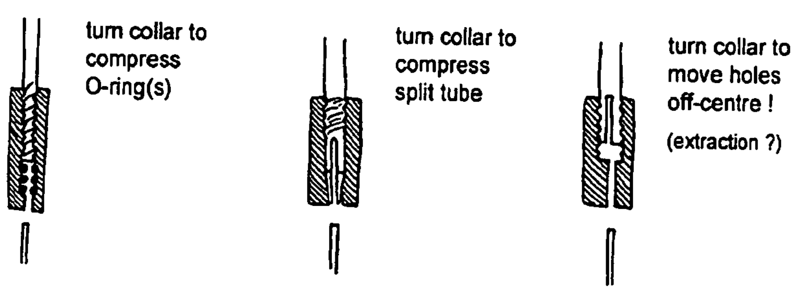
**Progress summary - clutch ideas**

## Clutch ideas for plain lancet...




**It appears that the smallest, lightest clutches will make use of a threaded collar. This would necessitate the introduction of a rotary action**

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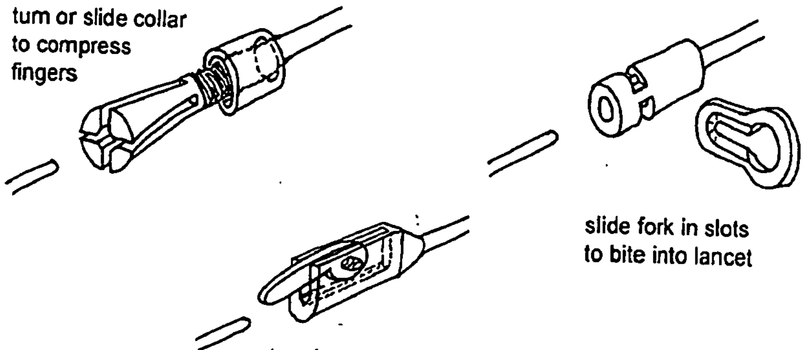
FIG_38

## Clutch ideas for plain lancet...








## View this slide after studying C6887-M-003, 'Lancet travel calculations'

**If lancets are pulled out of a storage strip by the engine, we need a lancet guard that stays "forward" when lancet is retracted to the firing position**

- otherwise lancet will be visible and vulnerable before use

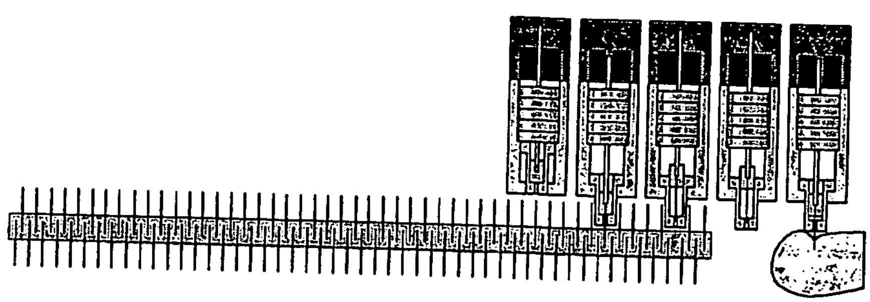
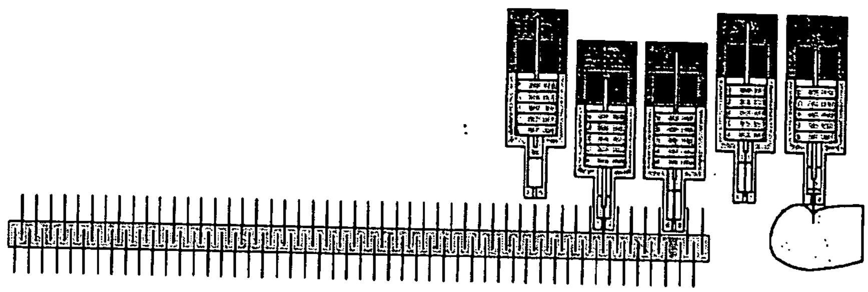




FIG_39

**If lancet guard is formed as part of engine housing, then whole engine assembly would need to move, to pull lancets out of a storage strip**

- this would need a second linear actuator, or a user-movement







**If lancet guard is formed as part of engine housing, and engine assembly *doesn't* move, then either :**

- lancet guard is slit to allow lancets to feed through by lateral movement, or
- strip must move "down/along/up" to feed (..can we get next lancet into hole?)

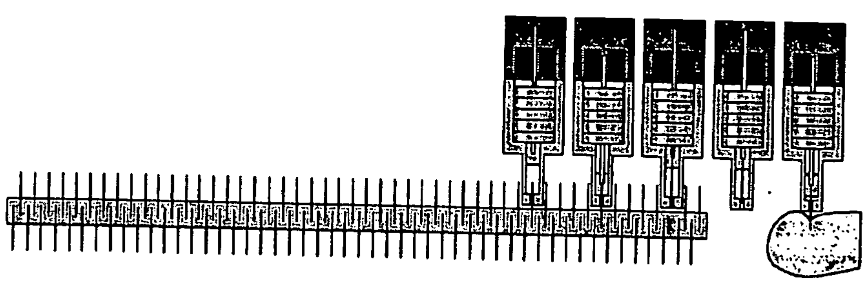
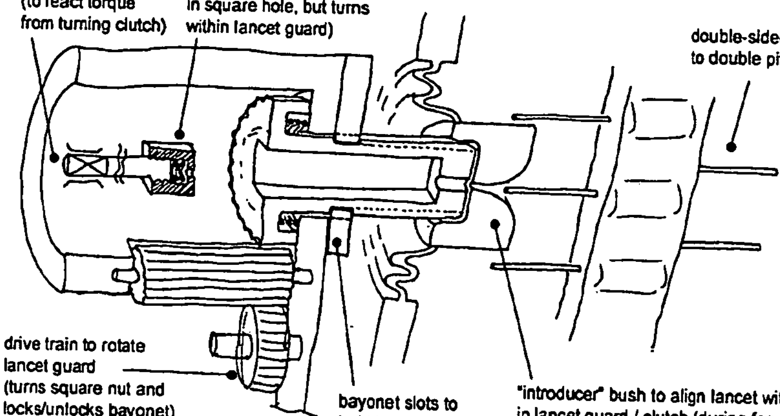




FIG - 40

**Progress summary** - one potential mechanism

## Combining the idea of a rotary actuated clutch with a moving lancet guard, suggests a core mechanism that looks something like this :

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**Progress summary** - solenoid manufacturing study

## We are creating a shortlist of appropriate suppliers for the complete assembly

- Suppliers being considered include
  - motor manufacturers
  - transformer manufacturers
- NDA's are being put in place prior to issue of drawings
- To maintain secrecy it was agreed that Pelikan's name would be removed from all drawings
- We are modifying drawings to release to suppliers
  - removing Pelikan references
  - creating assembly drawings with critical dimensions and details of assembly methods

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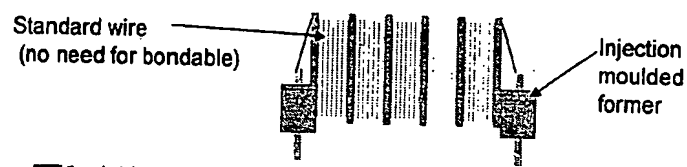
FIG_41

Progress summary - solenoid manufacturing study (continued)

**We have discussed the design and function of the actuator with Jim Ross and Don Alden. Initial suggestions to reduce cost are -**

- The coil housing can be made as a drawn cup rather than a turned component but the thin wall section makes this hard
  - Pelikan agreed an increase in end wall section from 0.2mm to 0.4mm should be acceptable (this may result in a slight increase in diameter).
- If the thin steel washers between the coils were to be eliminated then it may be possible to wind the entire coil assembly as a single component using transformer manufacturing technology
  - The steel sections between coils are very thin (0.2mm) and may be close to saturation during operation - will the actuator work without them?

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Progress summary - solenoid manufacturing study (continued)

**The coil commutation timing is influenced by the time required to allow the current to decay. With rotary reluctance machines it is common practice to use an asymmetric half bridge to force the coil current to zero in the shortest possible time - so improving high speed performance and power output. Component count can be reduced by sharing of switches (number of phases + 1)**

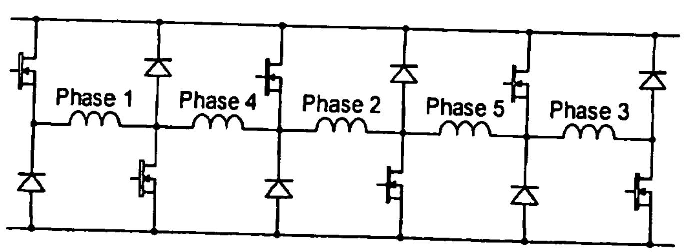


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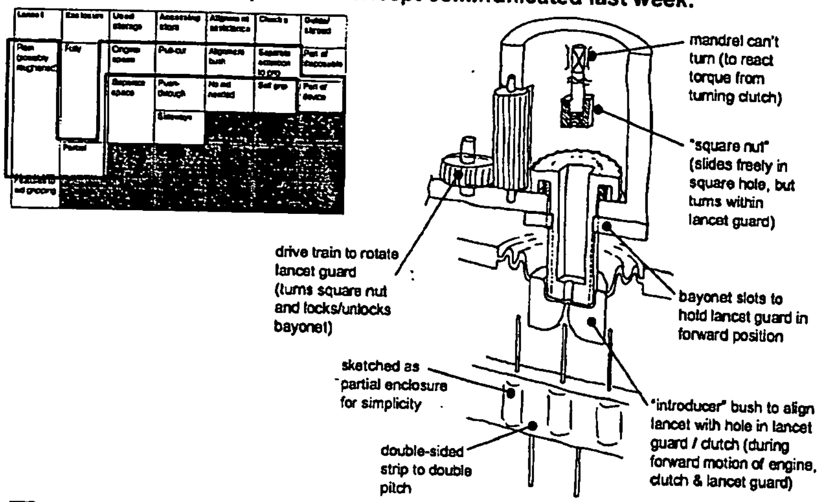
FIG - 42

Progress summary - more complete concepts generated

## We have built up two fairly complete core assemblies from our preferred ideas. The first is the pull-out concept communicated last week:

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Progress summary - more complete concepts generated (continued)

## A push-through concept:

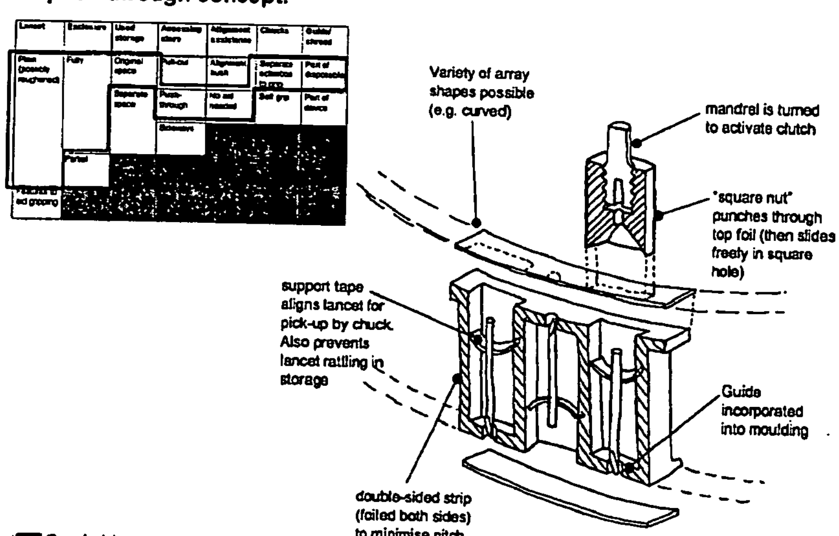


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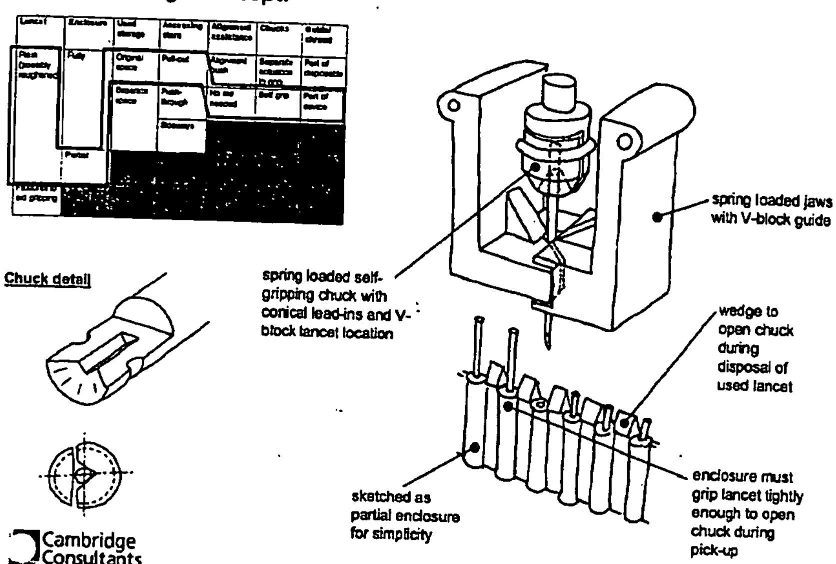
FIG_43

Progress summary - more complete concepts generated (continued)

## A push-through concept:

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Progress summary - lancet enclosure ideas...

## ...to be combined with one or more of the concepts in the previous slides

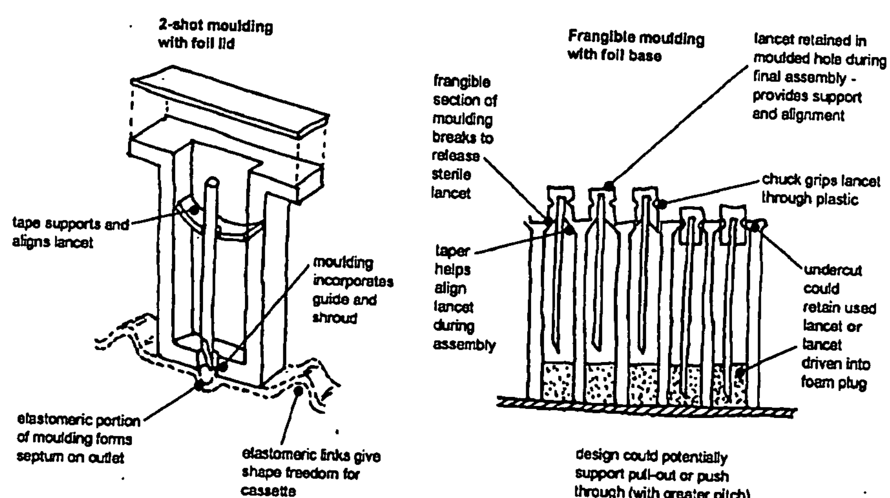


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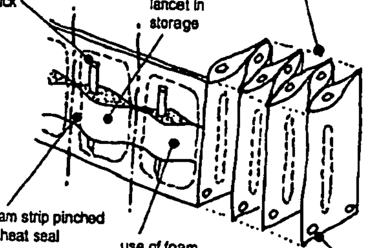
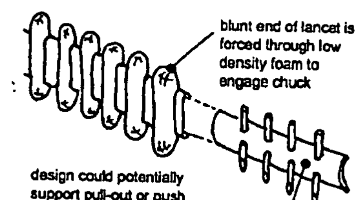
FIG. 44

Progress summary - lancet enclosure ideas... (continued)

## ...to be combined with one or more of the concepts in the previous slides

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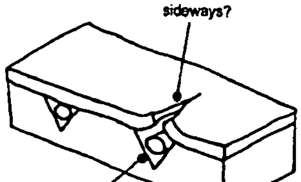
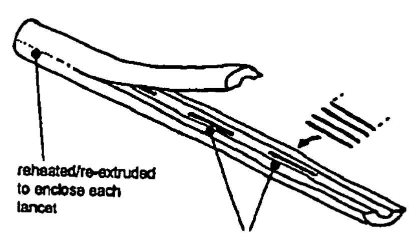
5 July 2002 14

Progress summary - lancet enclosure ideas... (continued)

## ...interesting but as yet incomplete ideas that may prove useful elsewhere

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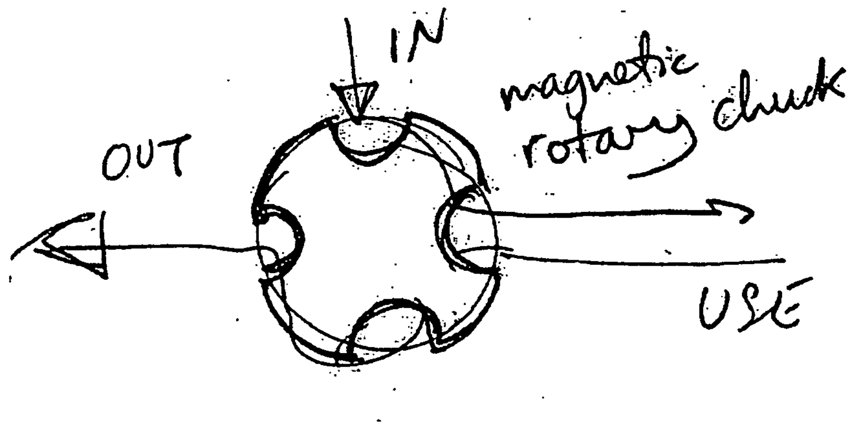
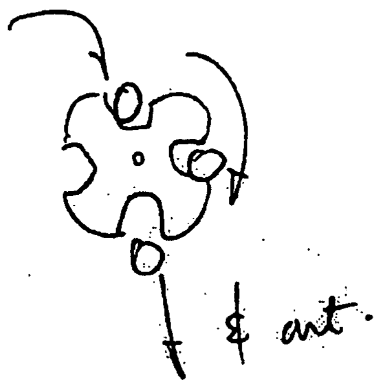
5 July 2002 15

FIG 45

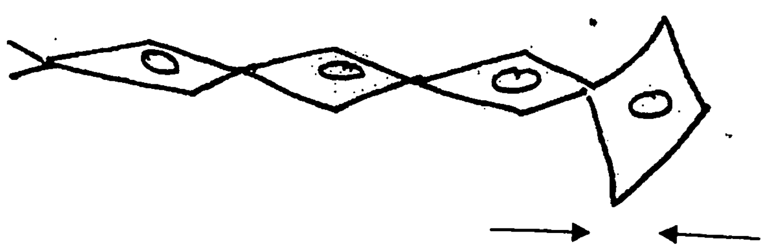
- Magnetic rotary chunk




- Bar/star feeder




- Corrugated carrier strip



Squeeze to release

FIG - 46

PELIKAN TECHNOLOGIES

## One brainstorm session looked at different ways to form useful retention features on the lancet, with minimal additional parts / operations

- This area of the Project is particularly challenging
  - reliability of attachment
  - lack of axial play?
  - low cost manufacturing
  - potential for scale-up within required timescales

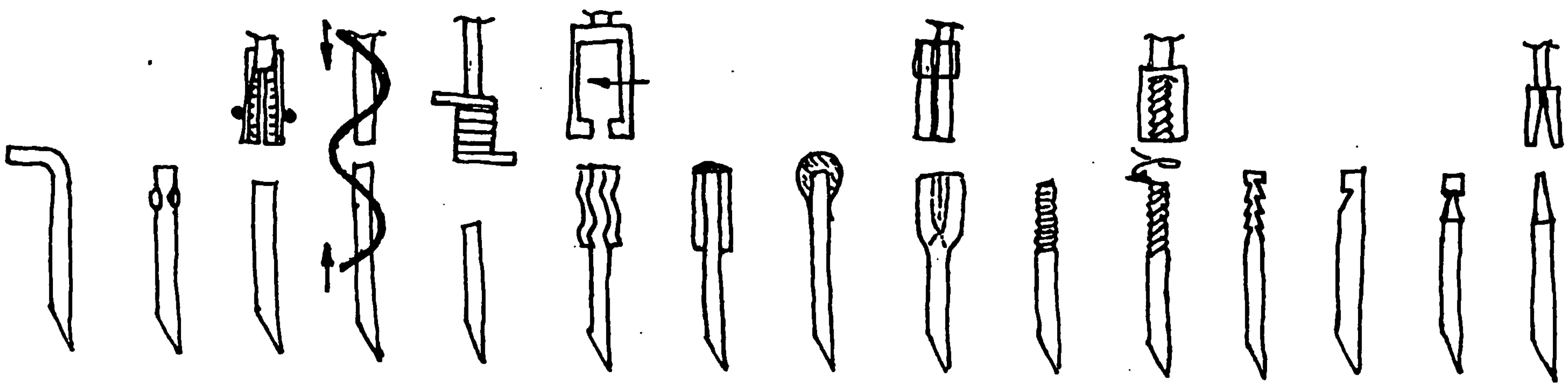


FIG_47

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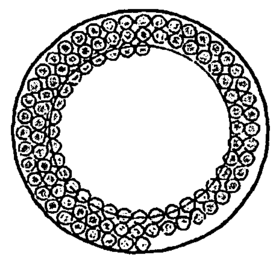
PELIKAN TECHNOLOGIES

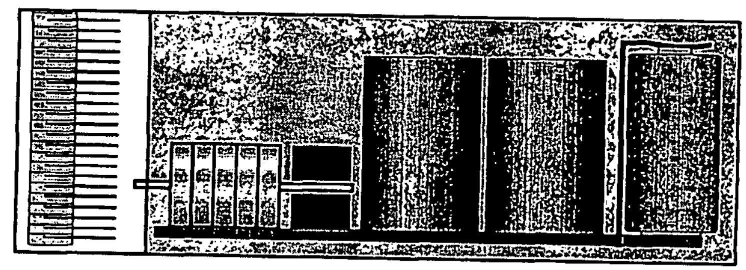
## Initial working concept #1 - spiral strip in cap/cassette

Spiral of 100 lancets in :
- flexible strip, or
- spiral grooves

Use cap/cassette removal to extract lancet from storage

Second motor to rotate mandrel &/or drive feed in cassette



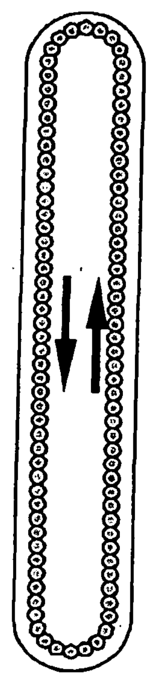


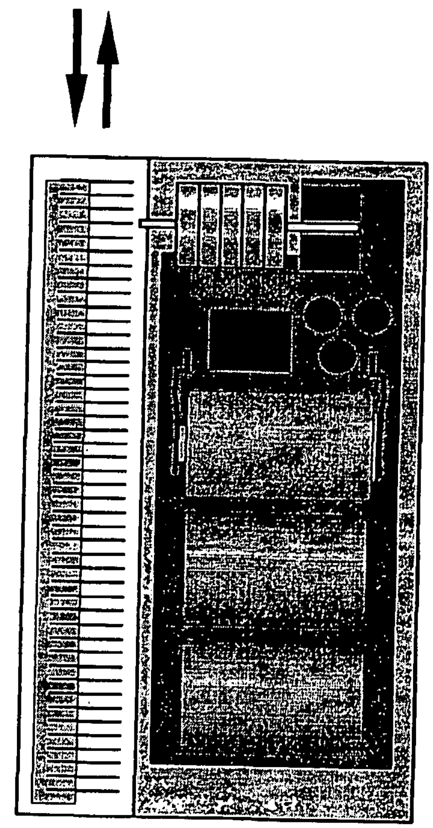
1. Attach mandrel to new lancet by :
   - axial movement (plus rotation ?)
   - perpendicular movement (= feed)
2. Remove cap, use device
3. Replace cap (lancet back in same hole)
4. Release used lancet :
   - retract mandrel, then feed, or
   - perpendicular movement (= feed)

FIG_ 48

## Initial working concept #2 - rolling belt/loop in cap/cassette

As #1, but with belt/loop feed in sliding cassette





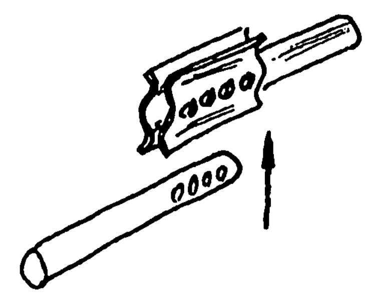


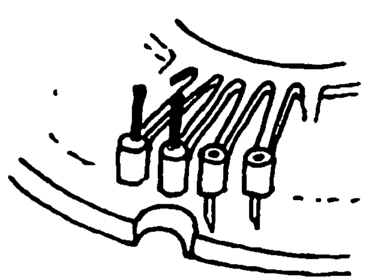
FIG 49

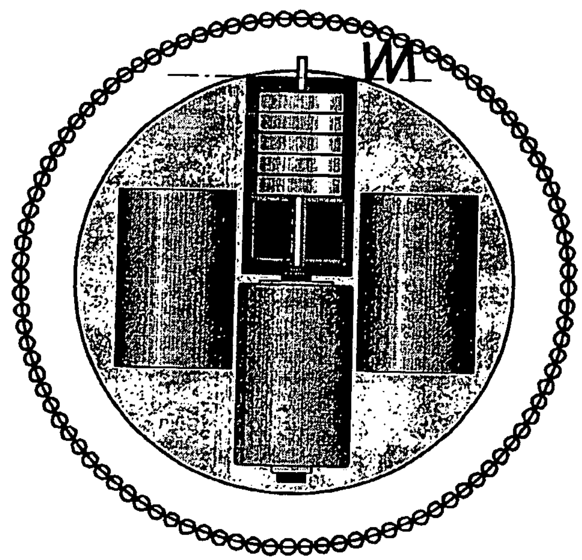
PELIKAN TECHNOLOGIES

## Initial working concept #3 - daisy-wheel in annular cassette

Rubber daisy wheel :
- lancet pushed through rubber to expose tip
- mandrel only pushes on lancet
- spring return retracts mandrel

Motor swings up for use, and folds flat for storage





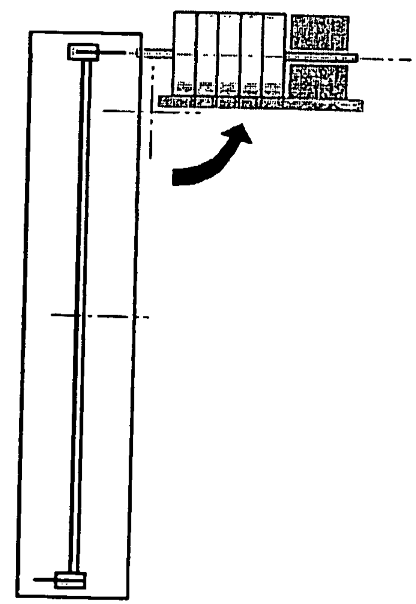
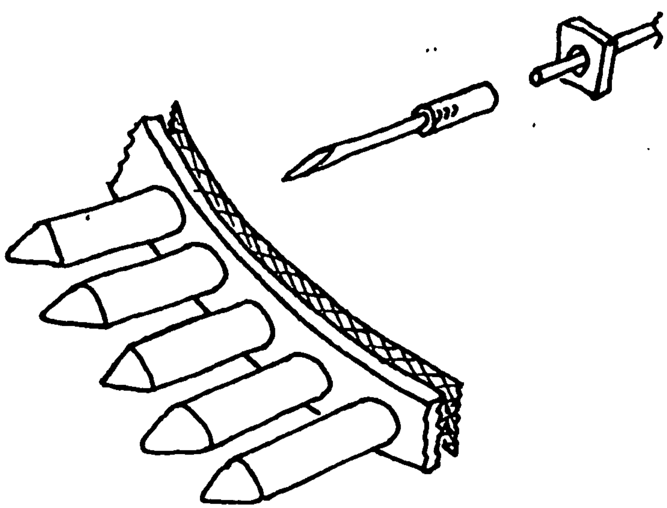


FIG-50

## Initial working concept #4 - radial "spokes" in annular cassette

Radial array of lancets in annular cassette :
- each lancet stored in individual foiled tube
- device forms central bobbin

double sided (2x50)
to double the pitch ?
- use 50 then turn over



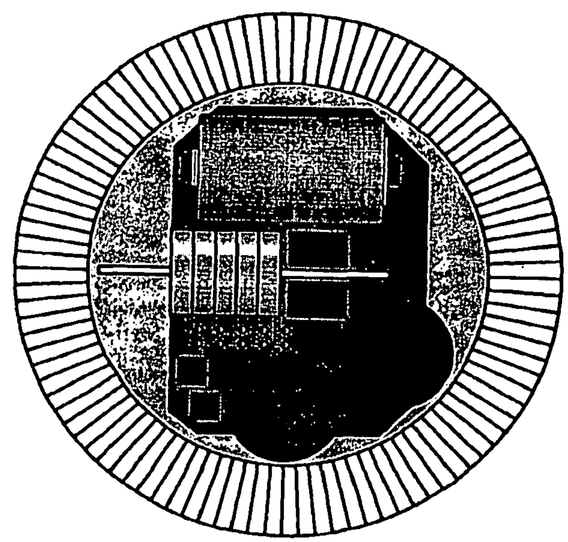


FIG_51

PELIKAN TECHNOLOGIES

## Initial working concept #5 - segmented rods in cap/cassette (pop-a-pencil)

Idea based on mechanical clutch pencil and wire strippers !

- 10 rods (Ø1) cut into 10 segments (6mm)
- stored in extruded drum with 11 slots - there is 1 extra slot to store waste
- after 10 lancets used, drum indexes to next slot (odometer drive gears)

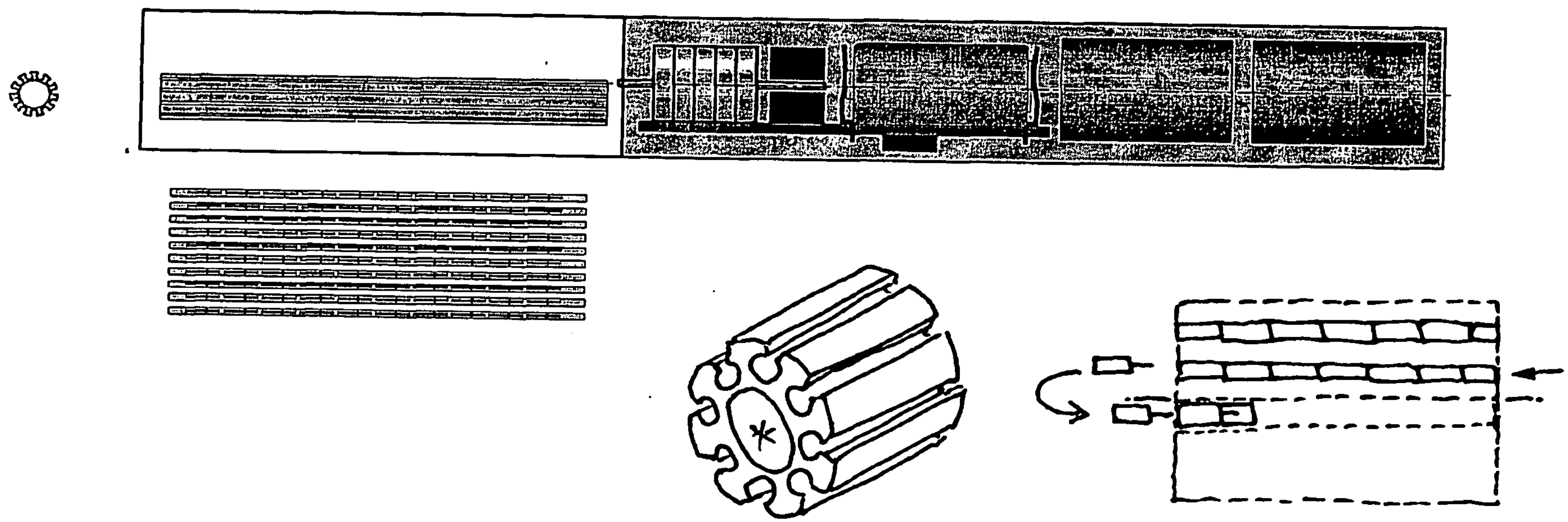


FIG-52

02033 System concepts v-001
24-06-02
D.Bradley

02033 VIPER PROJECT
21/06/02 D. Bradley
SYSTEM CONCEPT 1

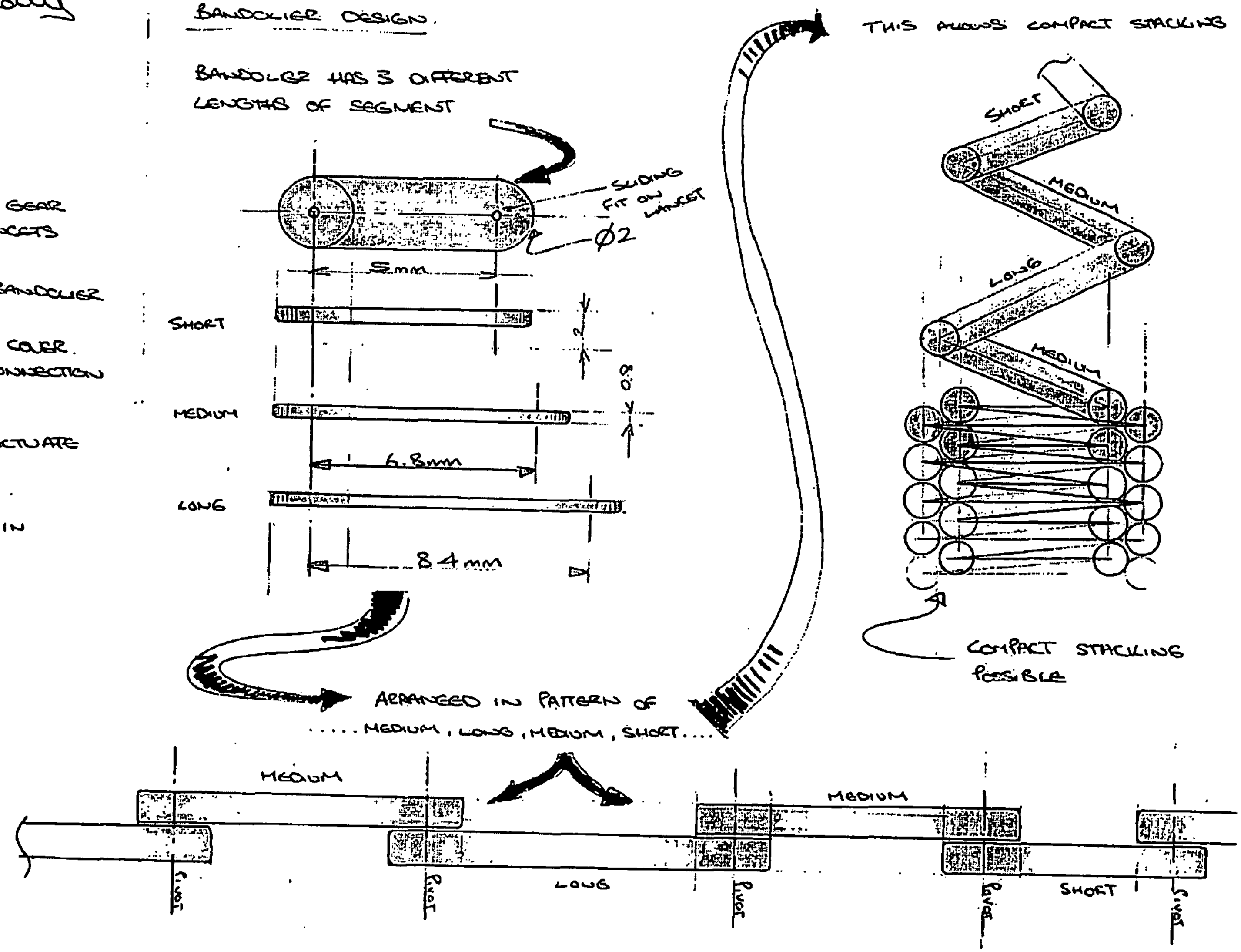
(1)

TOOLBOX USED

1. BANDOLIER OVER GEAR TO SEPARATE LANCETS
2. VARIABLE LENGTH BANDOLIER
3. LANCET WITH TIP COVER. AND NAIL HEAD CONNECTION TO ARMATURE
4. USER ACTION TO ACTUATE FEED SYSTEM
5. LANCET RETAINED IN BANDOLIER.

BANDOLIER DESIGN.

BANDOLIER HAS 3 DIFFERENT LENGTHS OF SEGMENT




4

FIG-53

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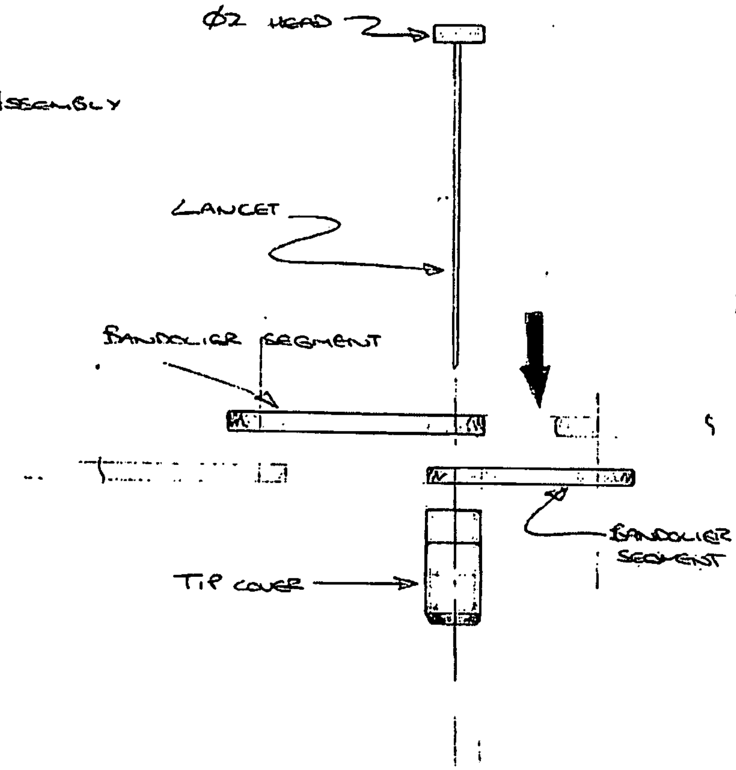
SYSTEM CONCEPT 1

(2)

LANCET INTO BANDOLIER

ASSEMBLY



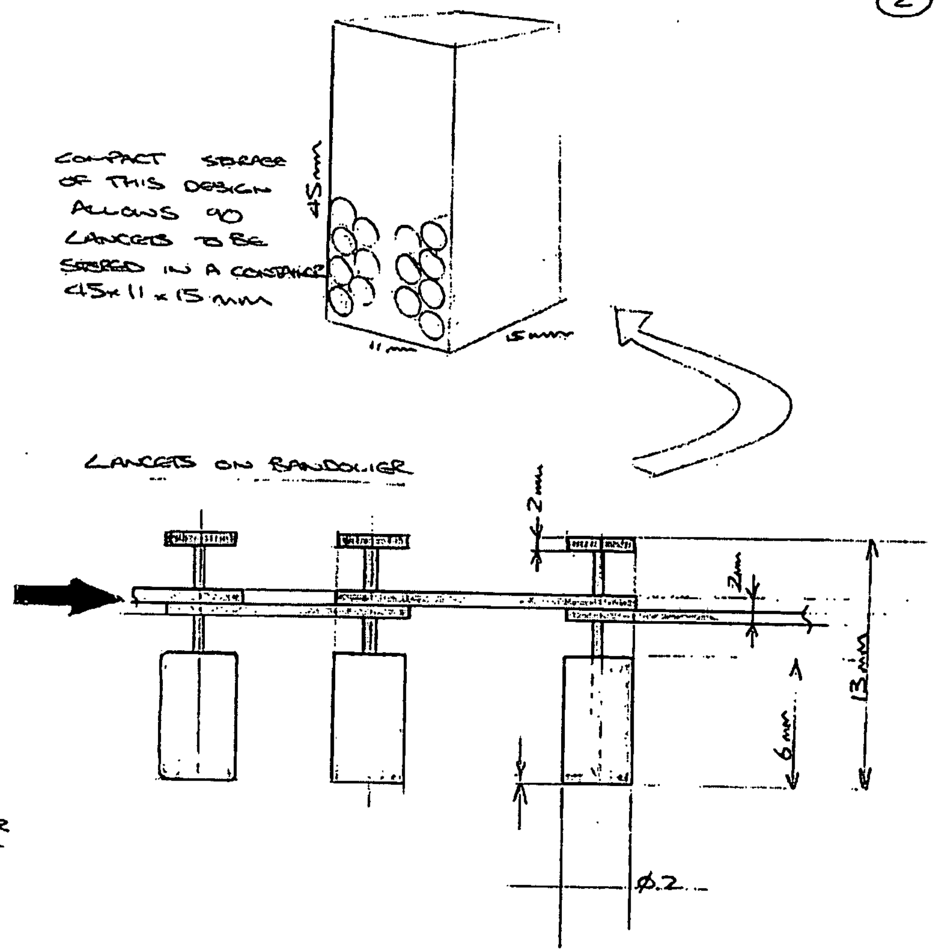




FIG_54

02033 System concepts v-001
24-06-02
D.Bradley

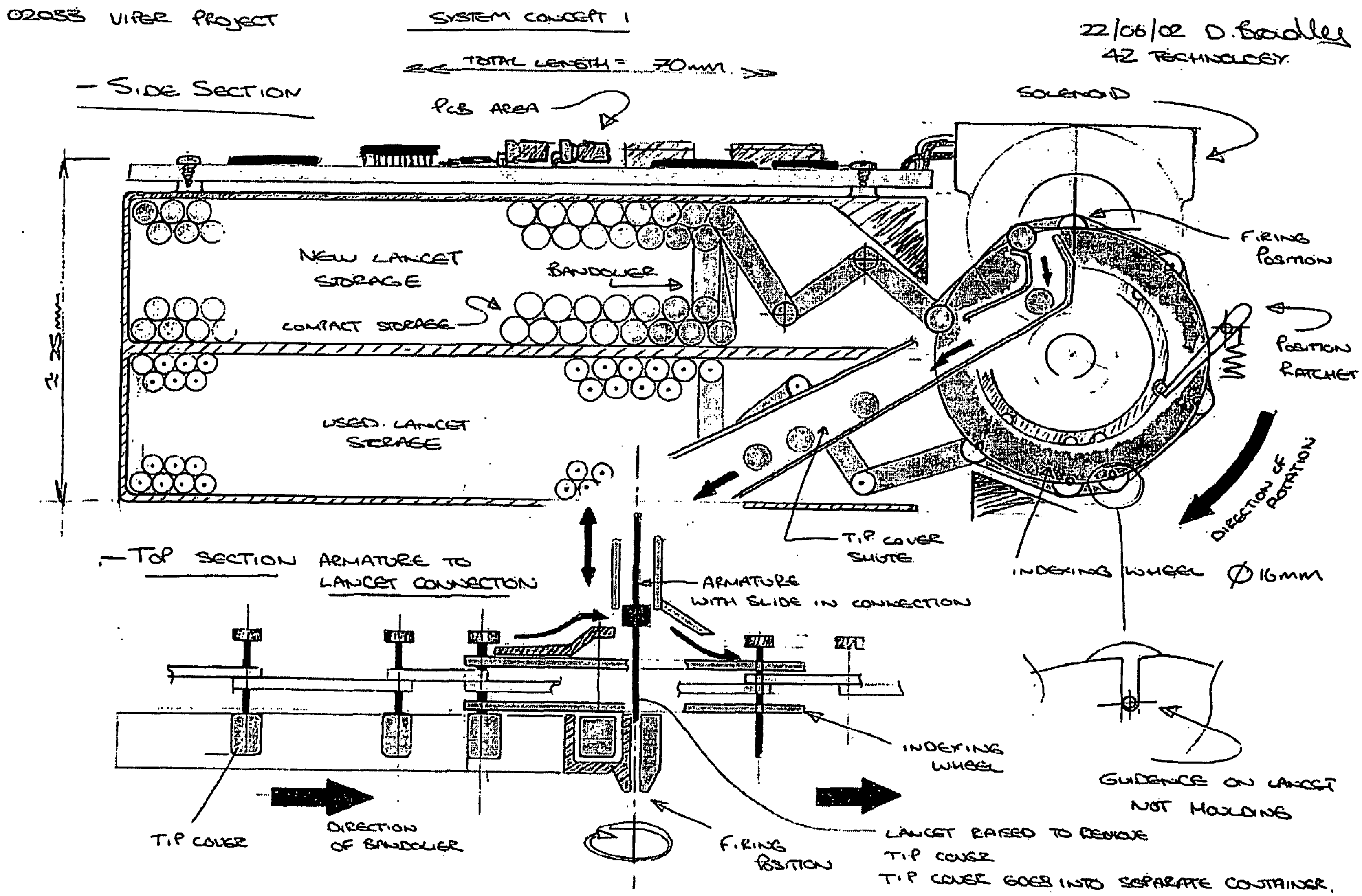



FIG_55

02033 System concepts v-001
24-06-02
D.Bradley

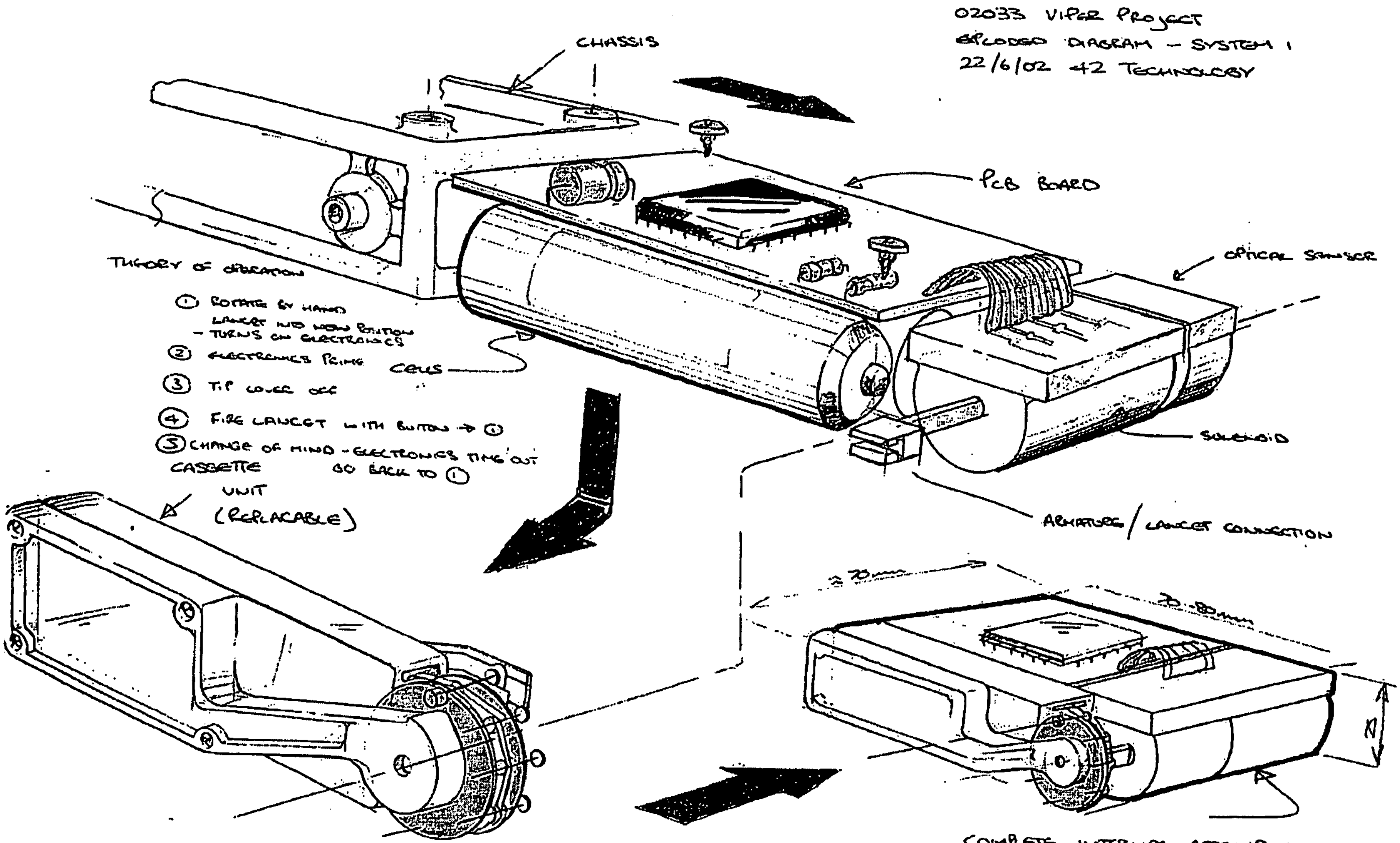



FIG-56

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CONCEPT 2 PAGE 1

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SYSTEM CONCEPT 2
42 TECHNOLOGY

TOOL BOX USED

1. CYLINDER CASSETTE
2. LANCETS ARRANGED IN SPIRAL
3. FOIL AND SPONGE SPIRAL SEALS
4. PLAIN LANCET
5. COLLET TYPE CONNECTION TO ARMATURE

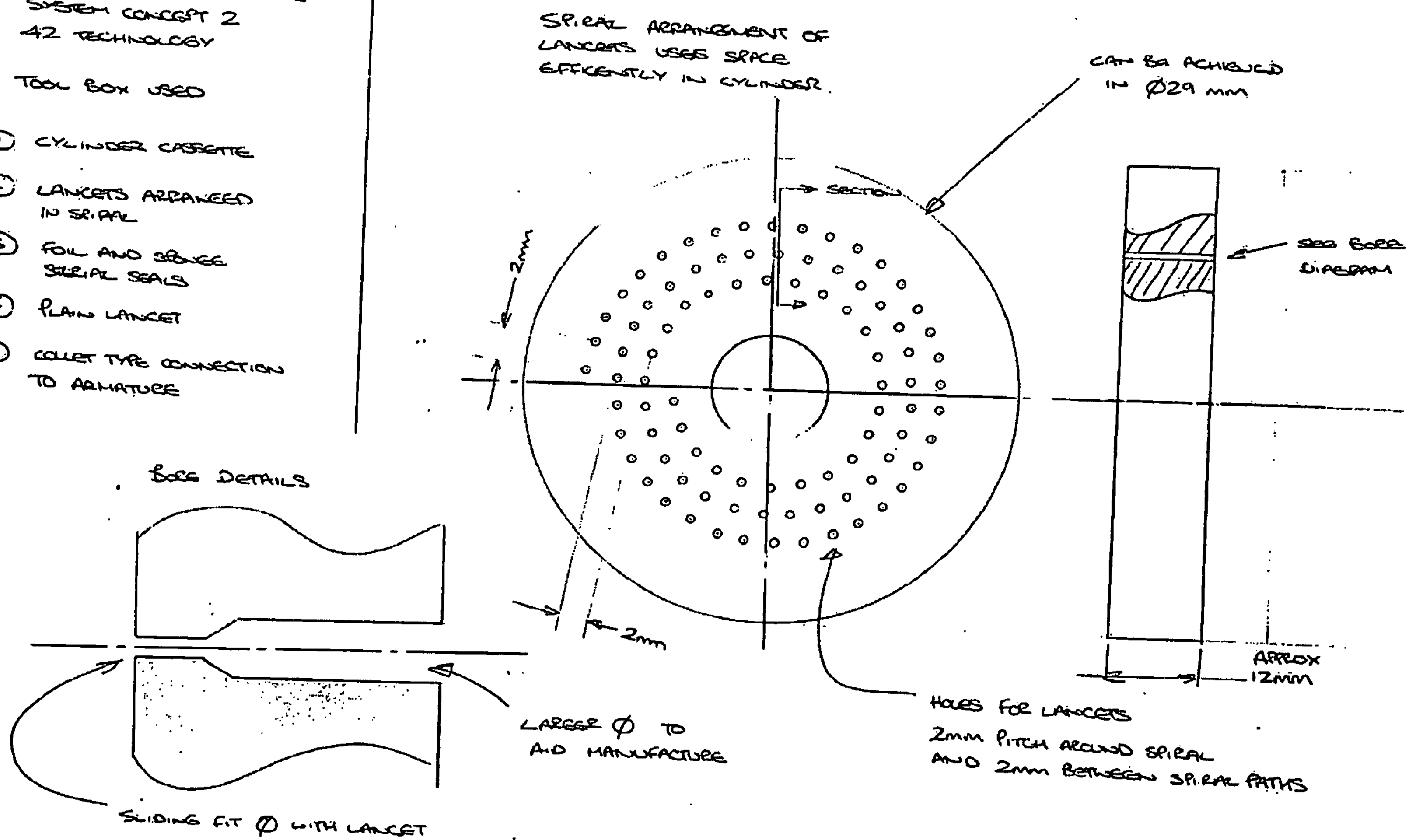


FIG_57

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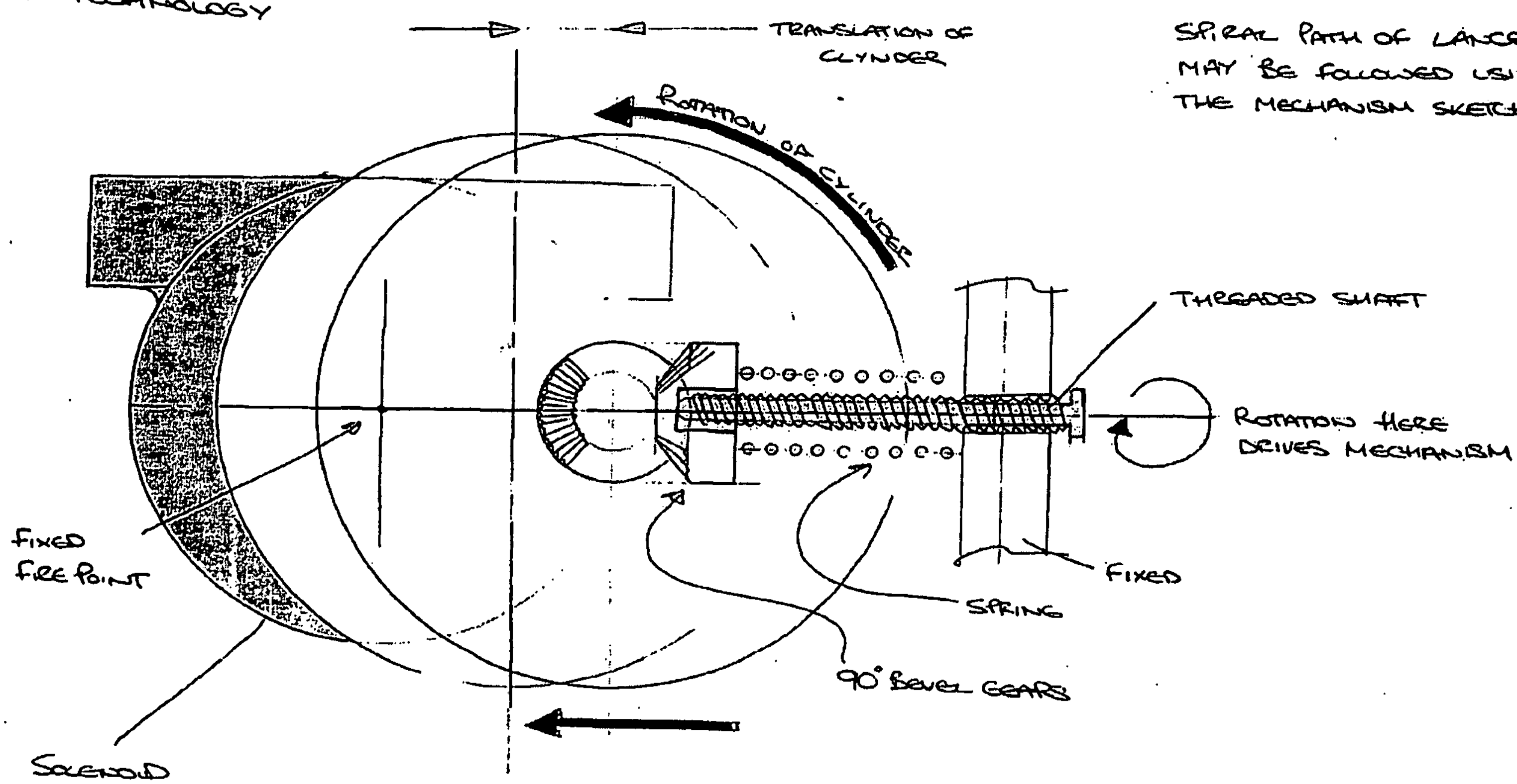
SYSTEM CONCEPT 2
42 TECHNOLOGY

CONCEPT 2 PAGE 2

SPIRAL PATH OF LANCETS MAY BE FOLLOWED USING THE MECHANISM SKETCHED.




TRANSLATION OF CYLINDER + ROTATION OF CYLINDER + FIXED FIRING POINT = SPIRAL LANCET ARRANGEMENT

FIG 58

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SYSTEM CONCEPT 2
42 TECHNOLOGY

CONCEPT 2 PAGE 3

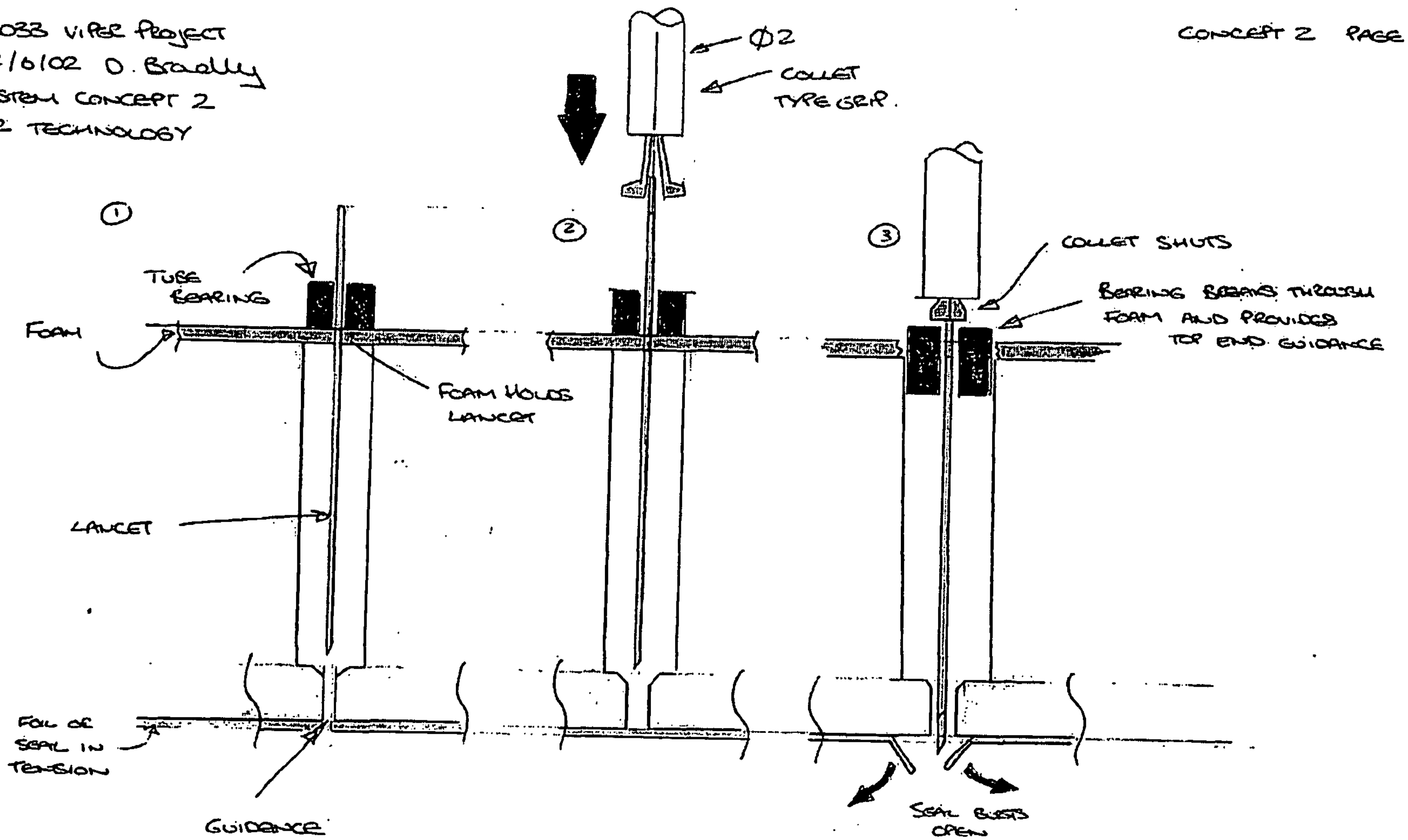


FIG_59

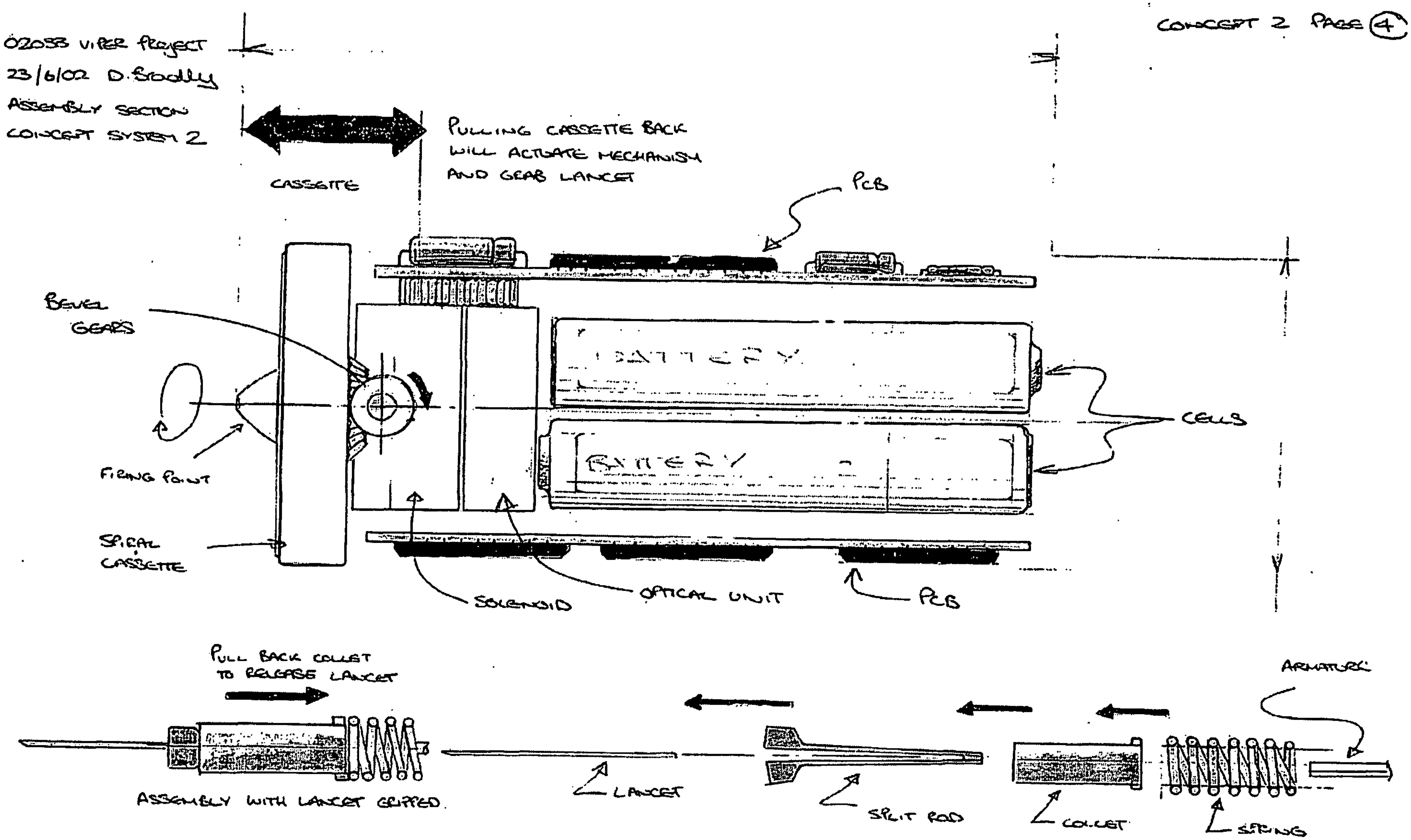
02033 VIPER PROJECT
23/6/02 D.Bradley
ASSEMBLY SECTION
CONCEPT SYSTEM 2
CONCEPT 2 PAGE 4
CASSETTE
PULLING CASSETTE BACK
WILL ACTUATE MECHANISM
AND GRAB LANCET
PCB
BEVEL
GEARS
BATTERY
BATTERY
CELLS
FIRING POINT
SPIRAL
CASSETTE
SOLENOID
OPTICAL UNIT
PCB
PULL BACK COLLET
TO RELEASE LANCET
ARMATURE
ASSEMBLY WITH LANCET GRIPPED
LANCET
SPLIT ROD
COLLET
SPRING

FIG-60

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22/6/02 D BRADLEY
42 TECHNOLOGY

SYSTEM CONCEPT 2

CONCEPT 2 PAGE 5

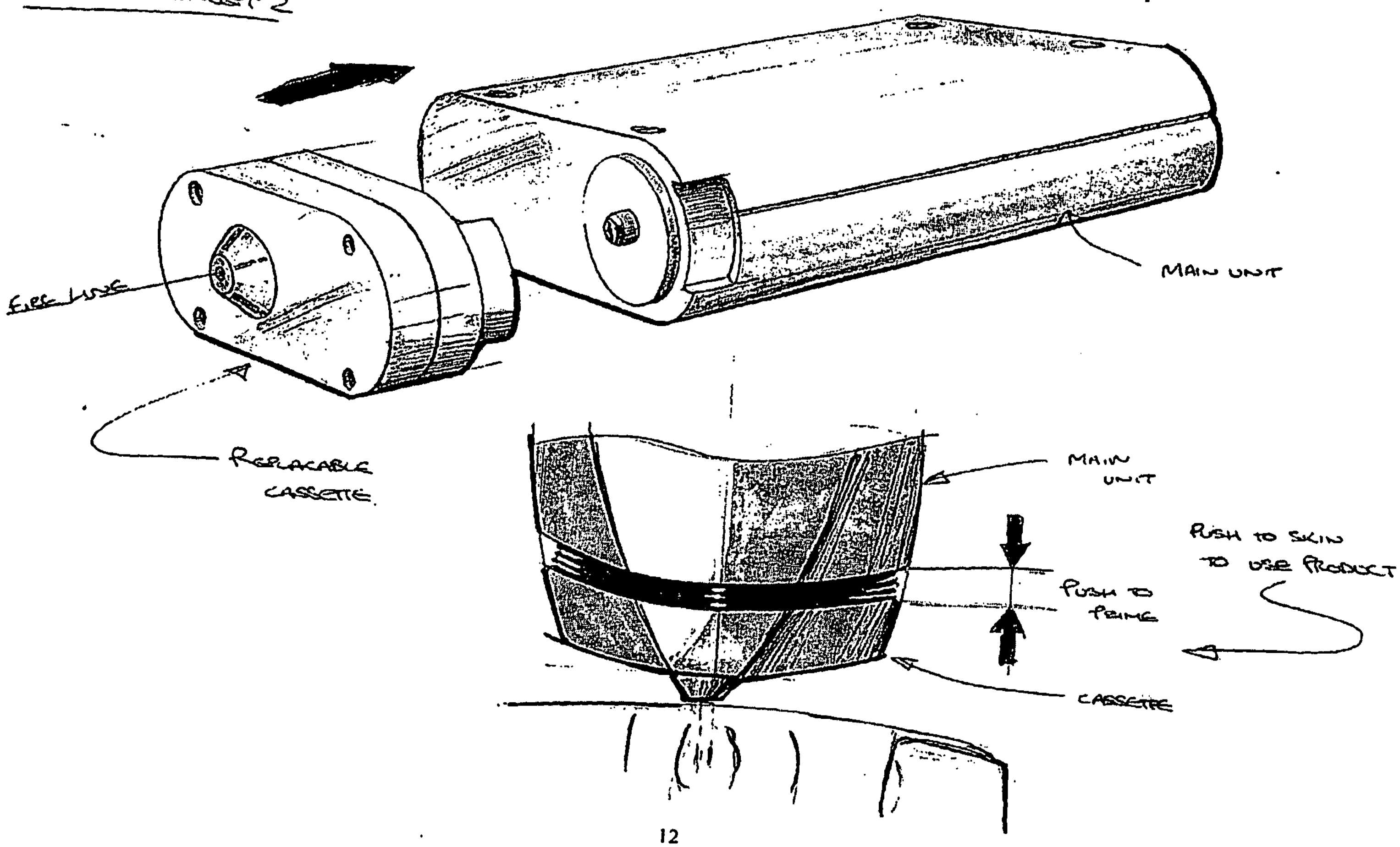
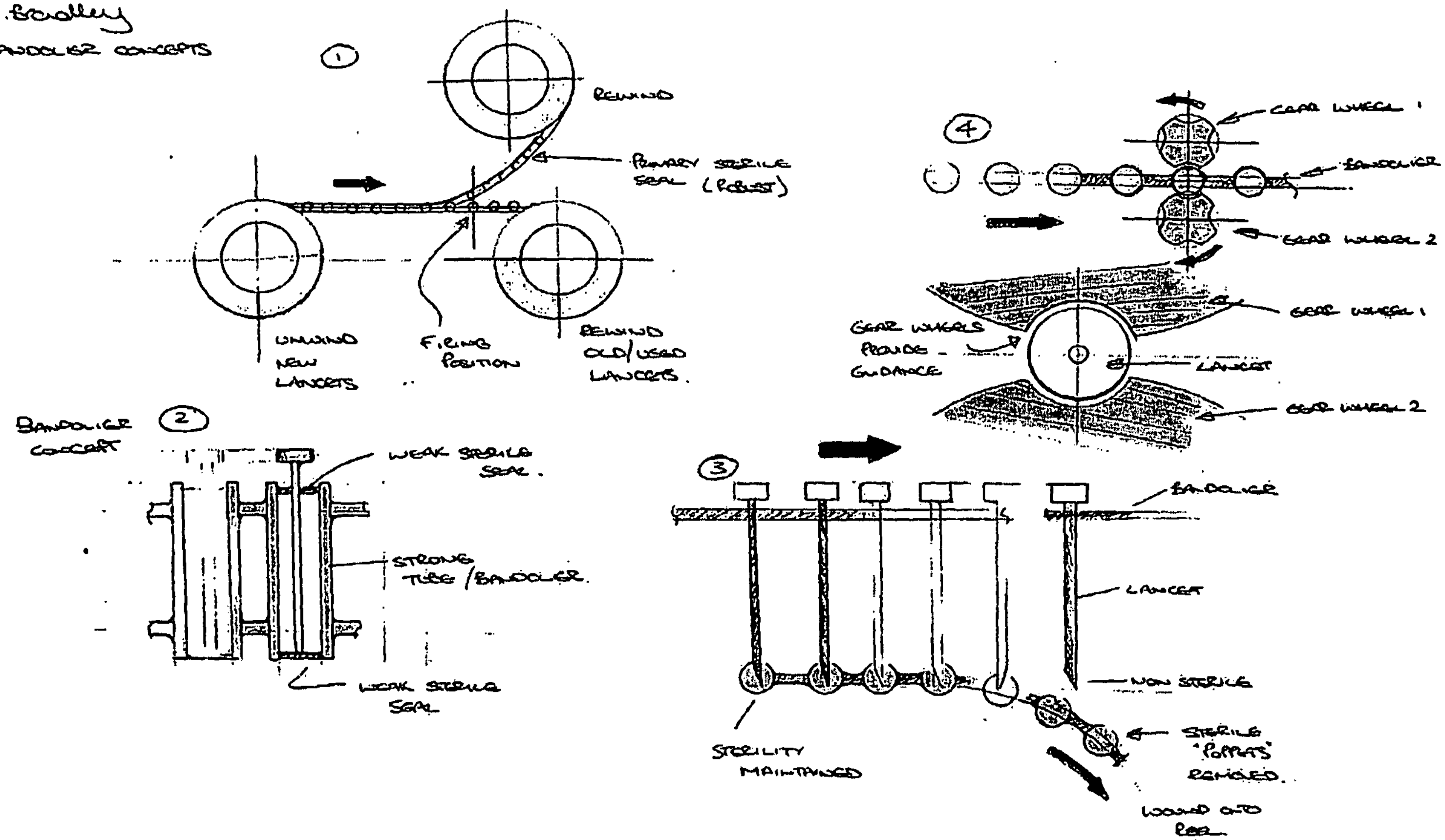





FIG_61

02033 Viper project
Workshop results 17-06-02

VIPER PROJECT 02033
13/06/02
D. Bradley
BANDOLIER CONCEPTS




1

2

FIG. 62

VIPER PROJECT 02033
18/6/02 D. Bradley
42 TECHNOLOGY

BANDOLIERS + POSSIBLE DESIGNS.

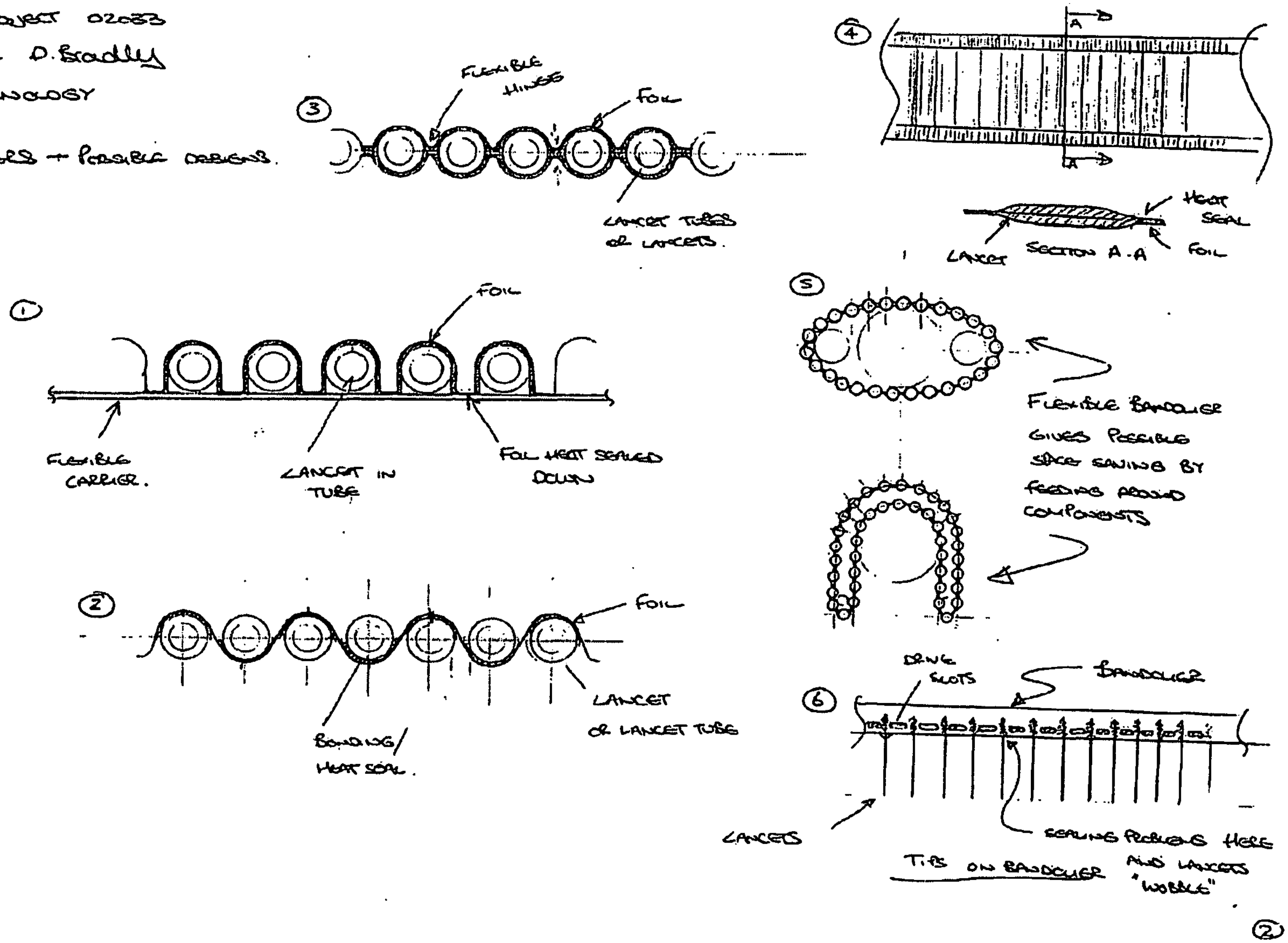



FIG-62

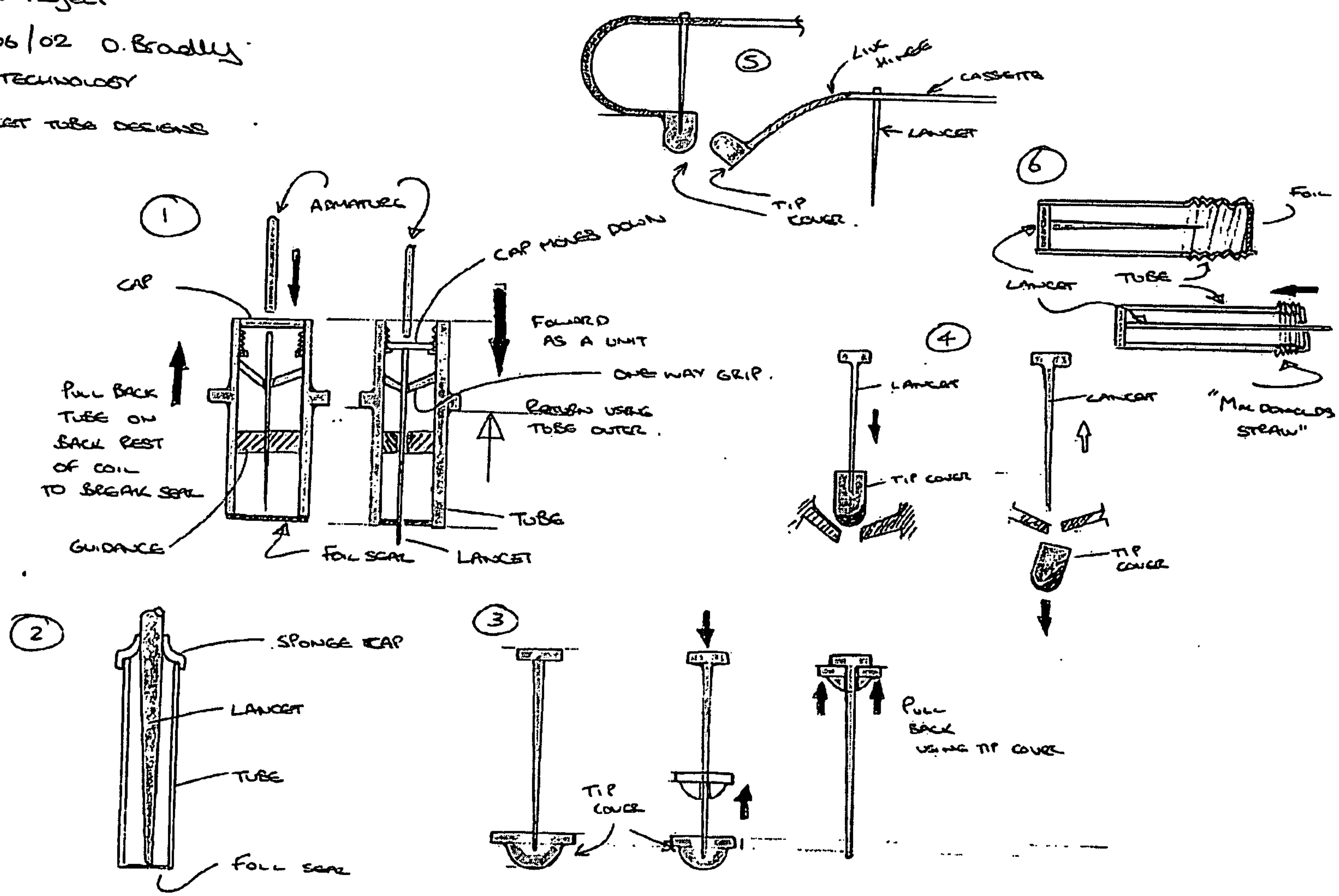
02033 Viper project
Workshop results 17-06-02

VIPER PROJECT

18/06/02 O. Bradley

42 TECHNOLOGY

LANCET TUBE DESIGNS



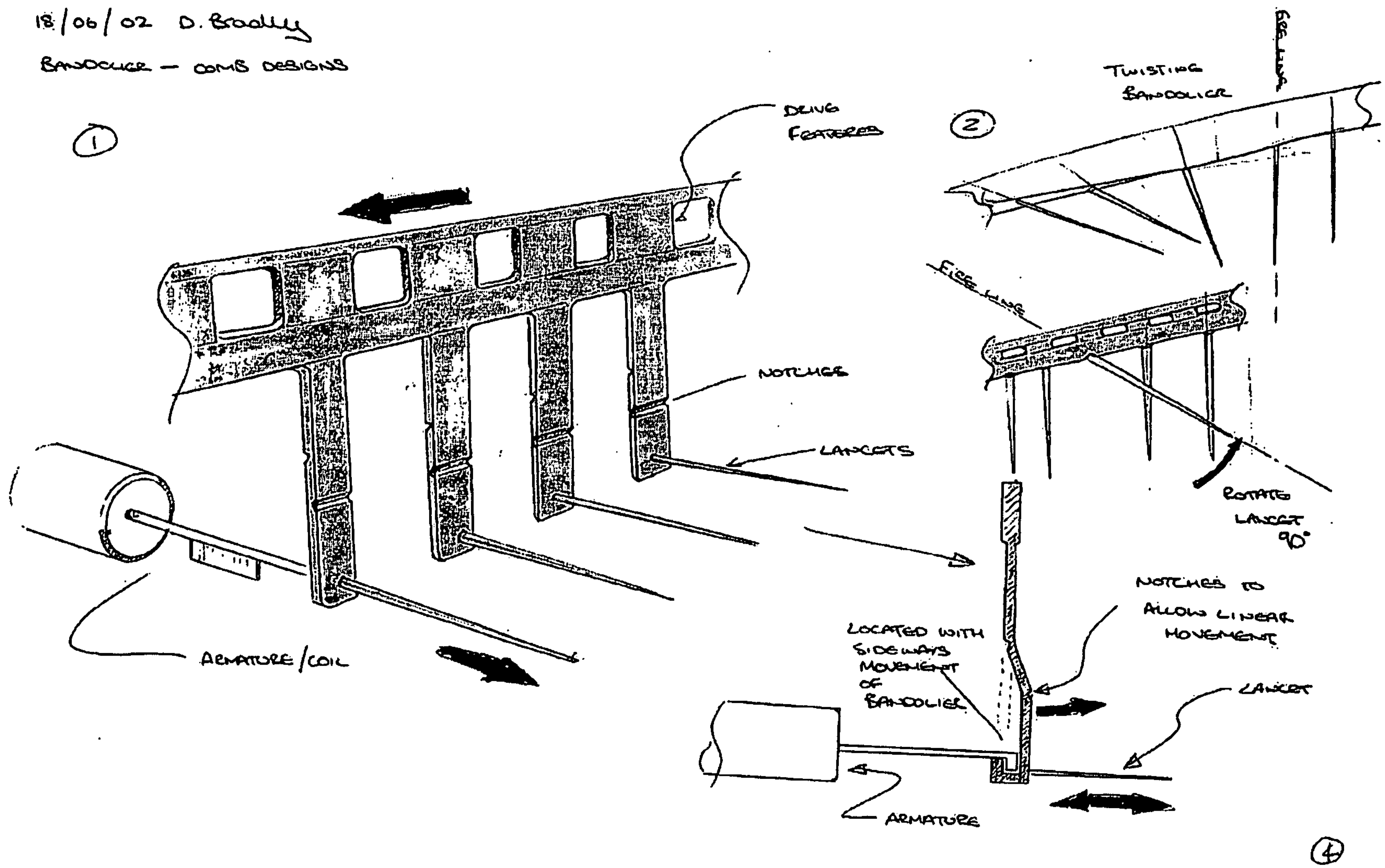

4

③

FIG_63

02033 Viper project
Workshop results 17-06-02

VIPER PROJECT 02033
18/06/02 D. Broadley
BANDOLIER — COMB DESIGNS




5

FIG_64

02033 Viper project
Workshop results 17-06-02

VIPER PROJECT 02033
18/6/02 D. Bradley
42 TECHNOLOGY
POSSIBLE CYLINDER DESIGNS

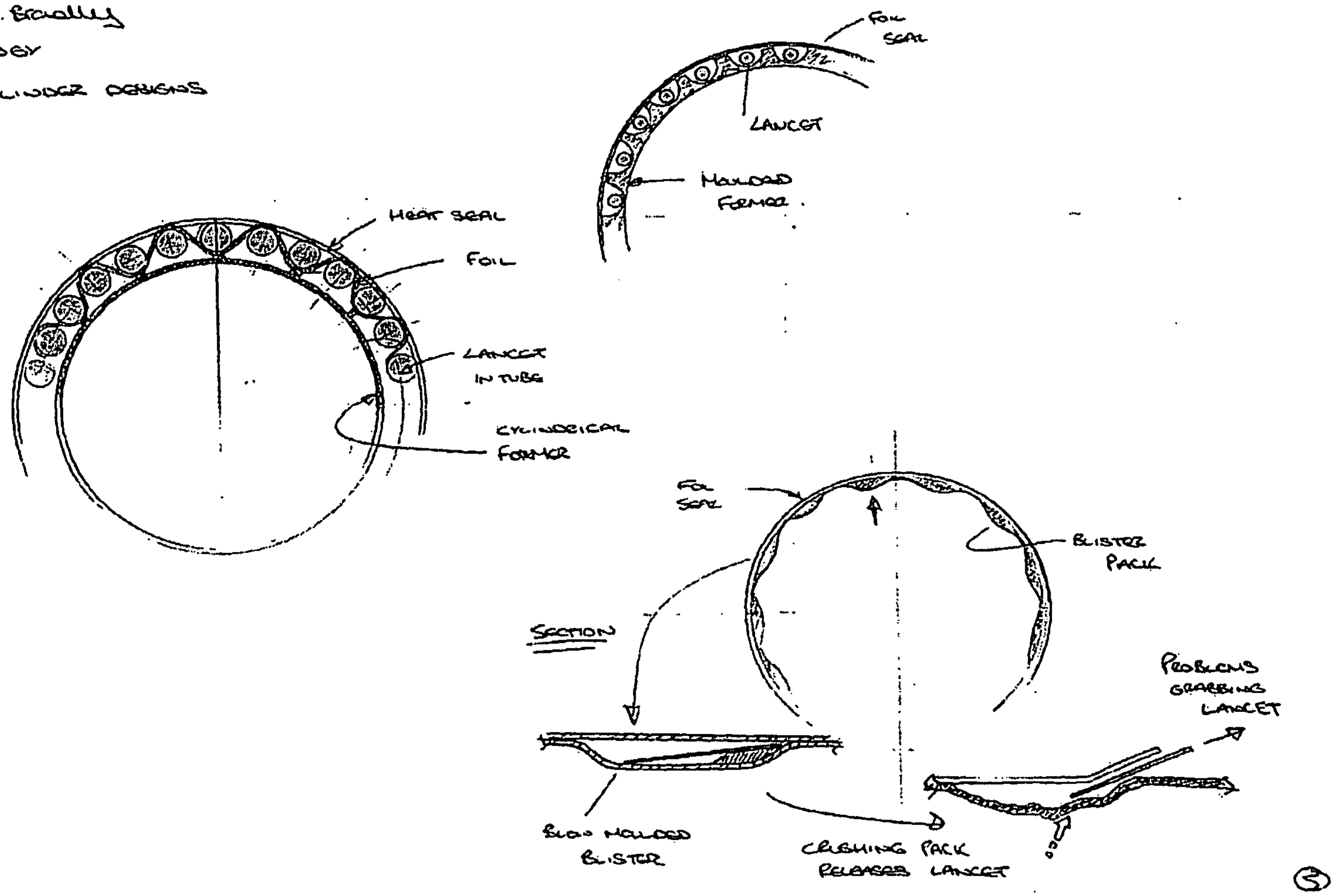
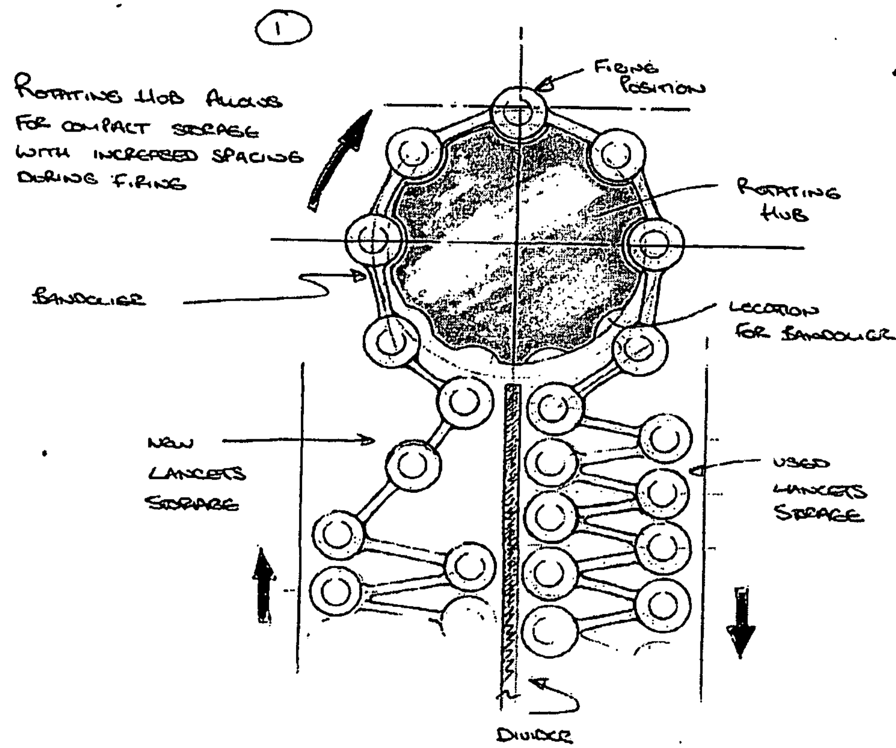
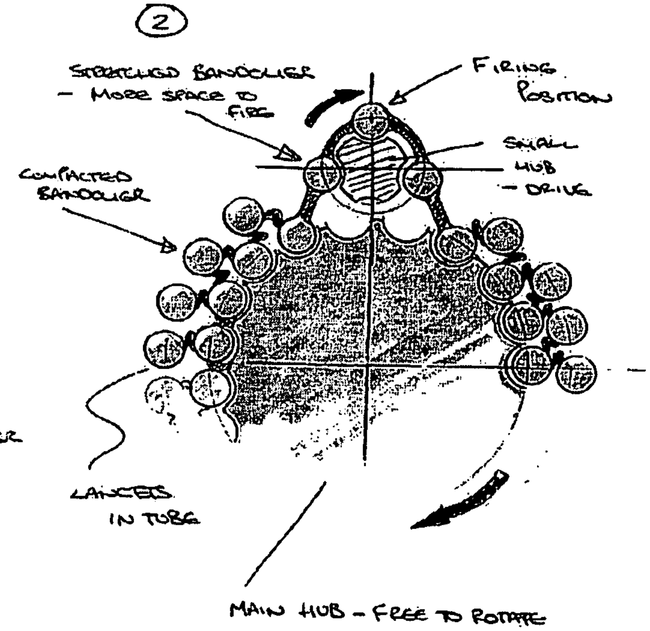



FIG_65

02033 Viper project
Workshop results 17-06-02

VIPER PROJECT 02083
18/6/02 D. Bradley
42 TECHNOLOGY
BANDOLIERS




A SECOND CONCEPT FOR COMPACT STORAGE WITH INCREASED SPACE FOR FIRING

6



FIG_86

02033 Viper project
Workshop results 17-06-02

VIPER PROJECT 02083
18/6/02 D. Bradley
42 TECHNOLOGY
CYLINDER CONCEPTS

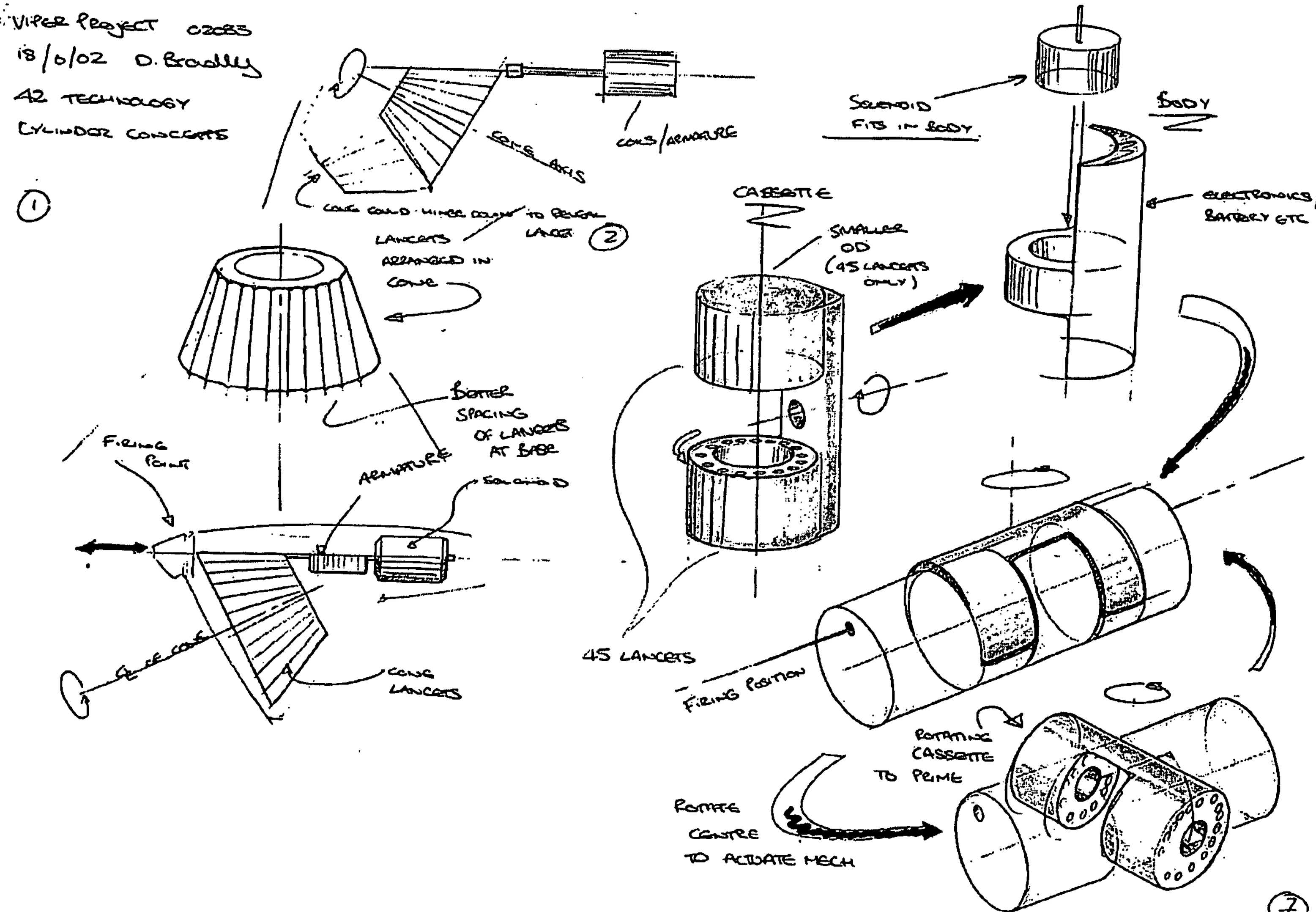


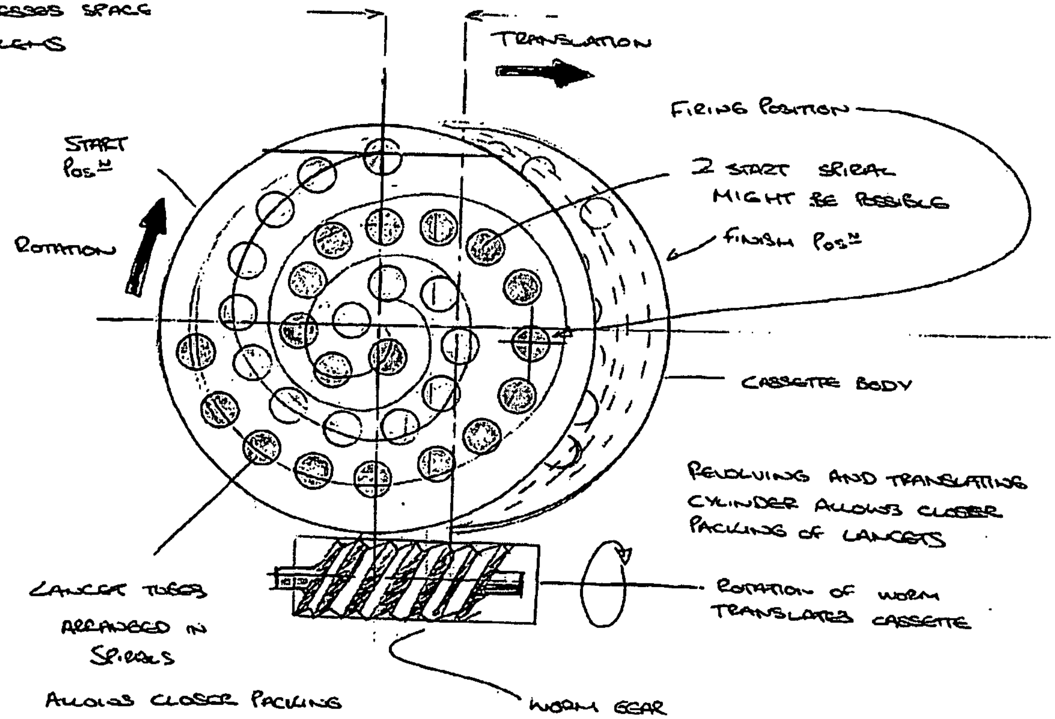



FIG_67

02033 Viper project
Workshop results 17-06-02

VIPER PROJECT 02033
18/06/02 D. Scrolly
42 TECHNOLOGY
SPIRAL REVOLVER
ADDRESSES SPACE
PROBLEMS

1



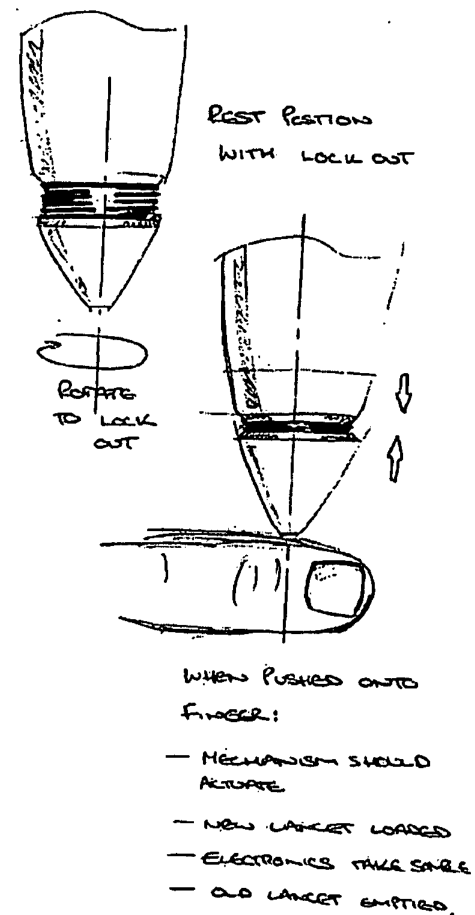




FIG-68

02033 Viper project
Workshop results 17-06-02

VIPER PROJECT – 42TECHNOLOGY
13/06/02 02033
D. [illegible]

RADIAL DISC SYSTEM

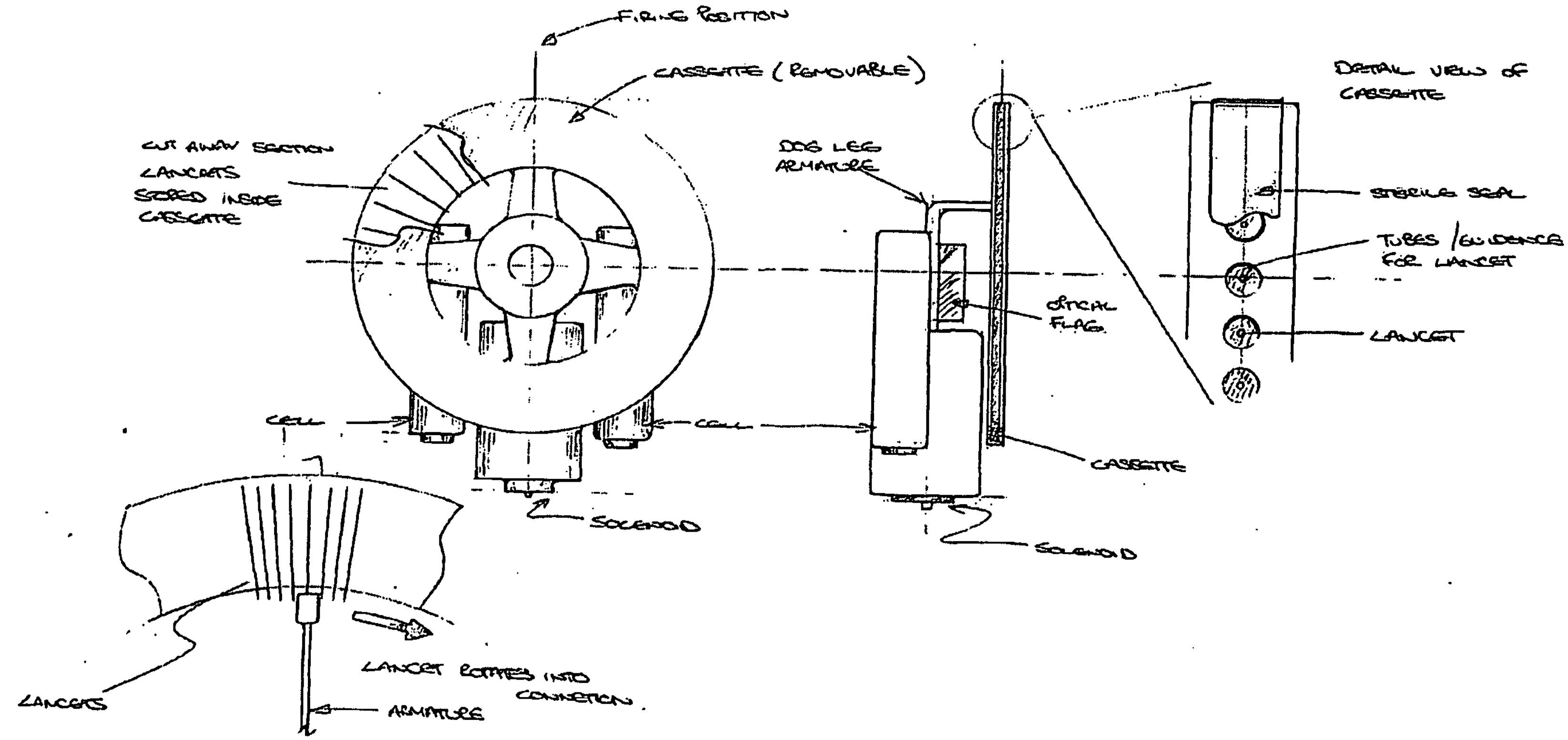



FIG-69

⑨

02033 Viper project
Workshop results 17-06-02

VIPER PROJECT 02033
18/6/02 D. Bradley
42 TECHNOLOGY
FEELER GAUGE TYPES

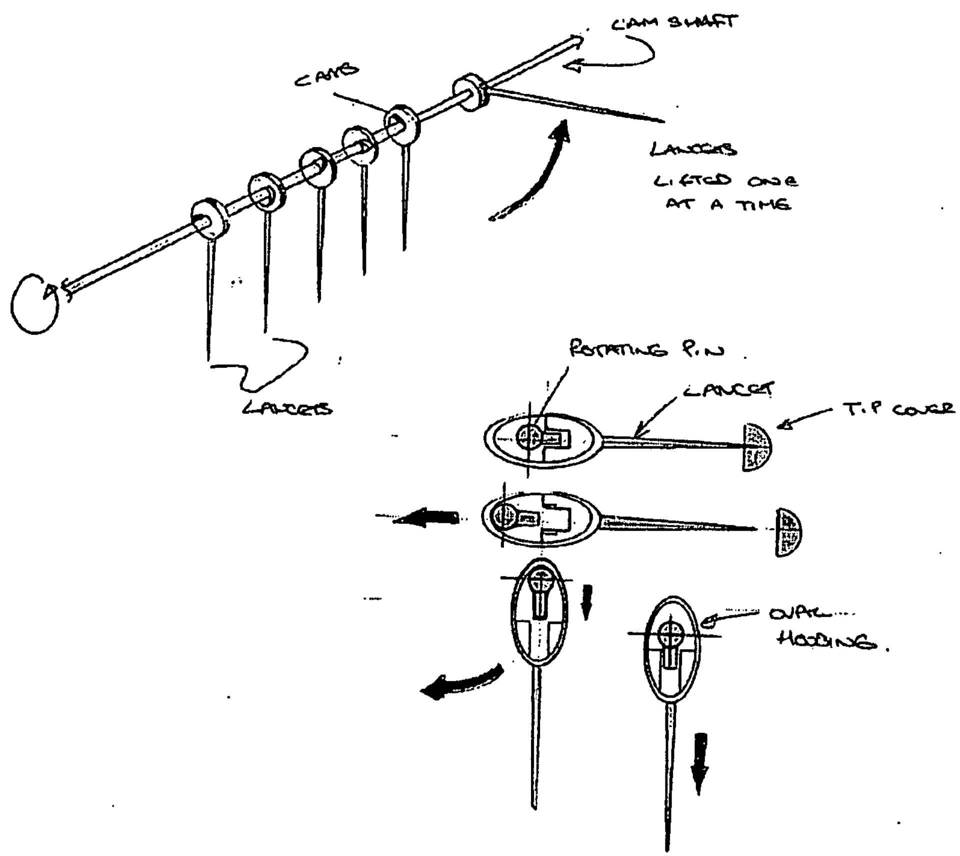



FIG_70

(10)

02033 Viper Project

42 Technology

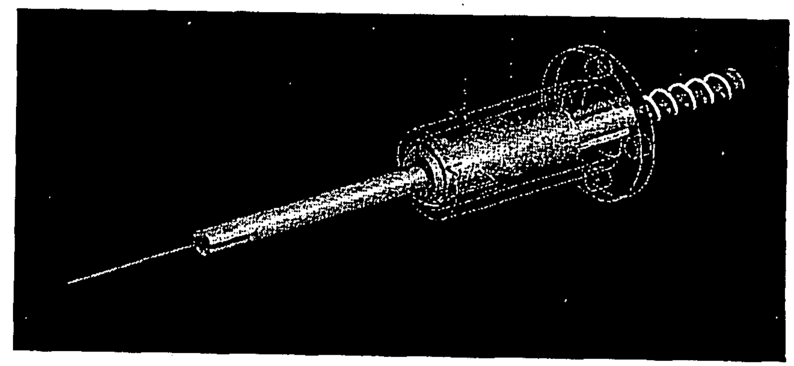
CAD Concept 2 for Review 3-06-02

2nd July 2002

Prepared by D.Bradley

1

1. Lancet connection mechanism

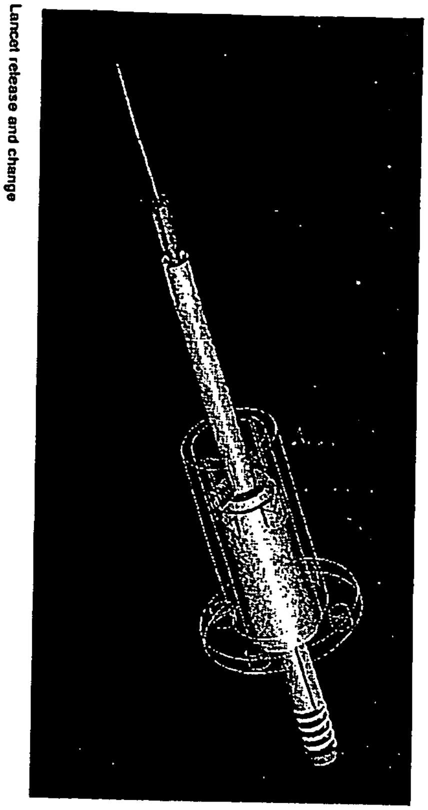


Lancet start

2

FIG-71

Lancet release and change



New lancet grip

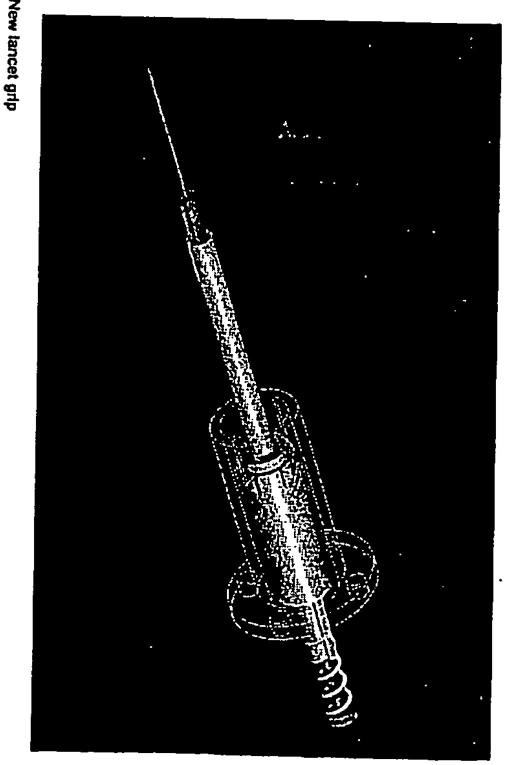
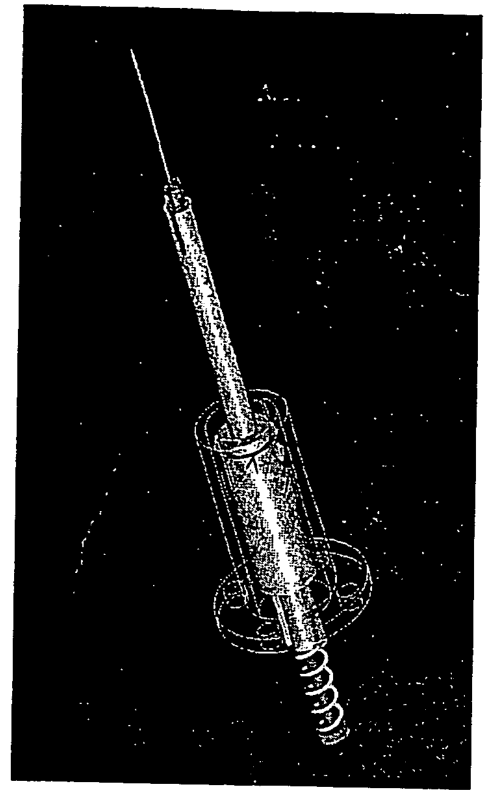


FIG - 72

New lancet tighten



Solenoid fire

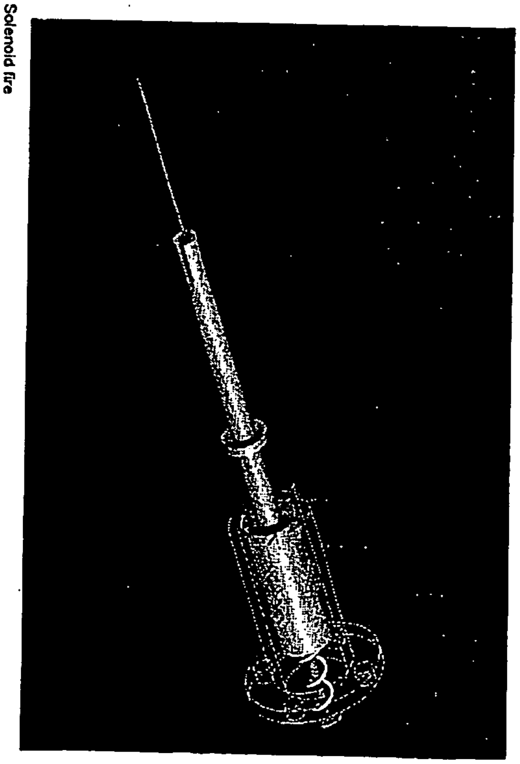
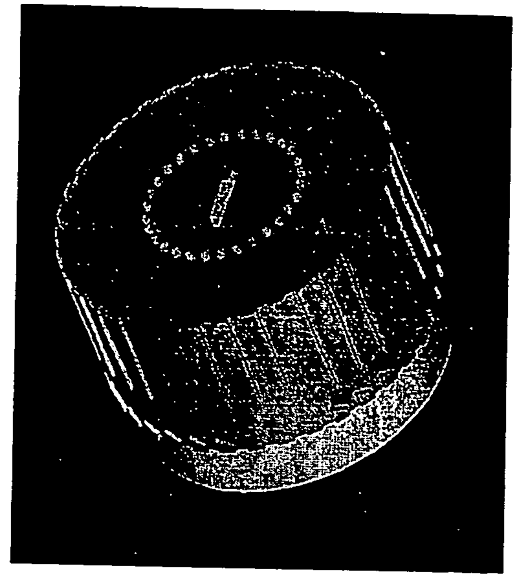


FIG_73

2. Cassette

Replaceable item



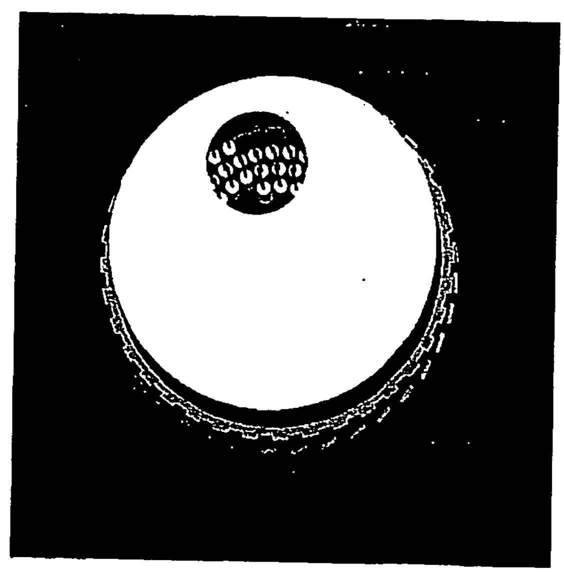
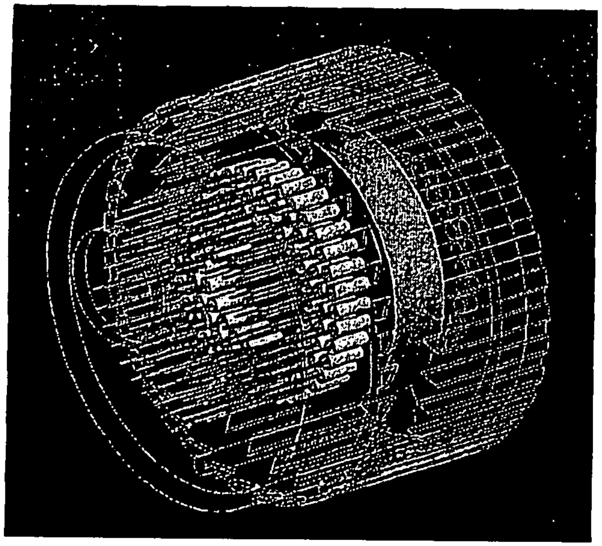
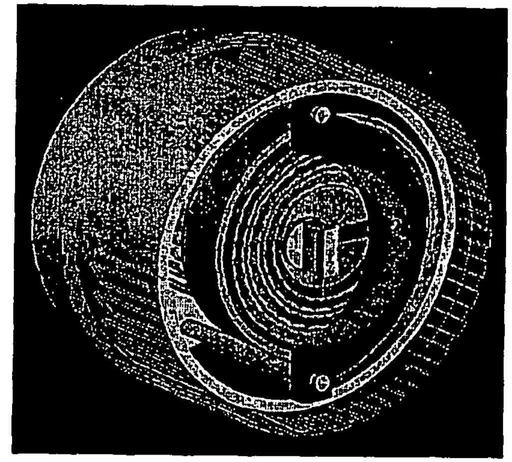


FIG. 74





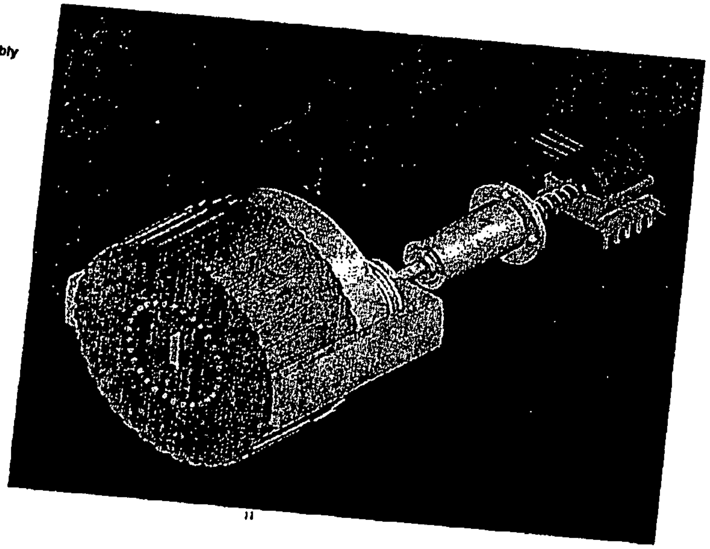


Detent pin runs in spiral groove – spiral cylinder moves from right to left. Fire position remains same place. Connection to outer cylinder achieved with Oldham Coupling.

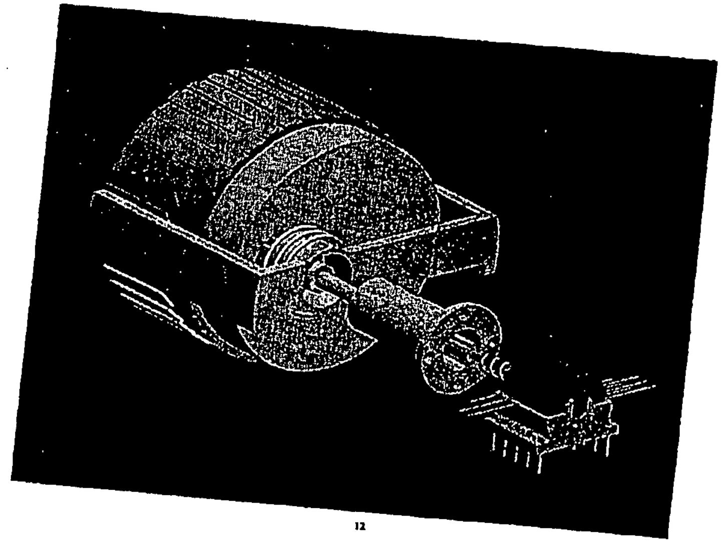


FIG-75

3. Assembly

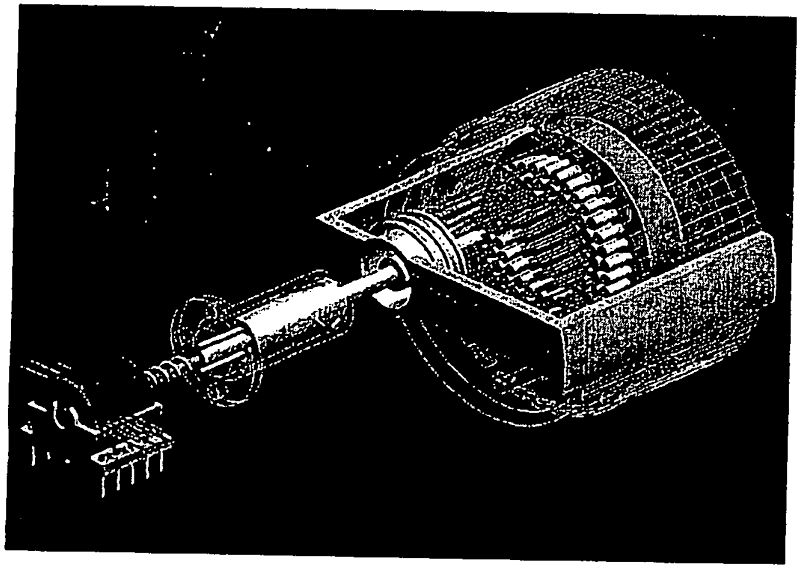


11



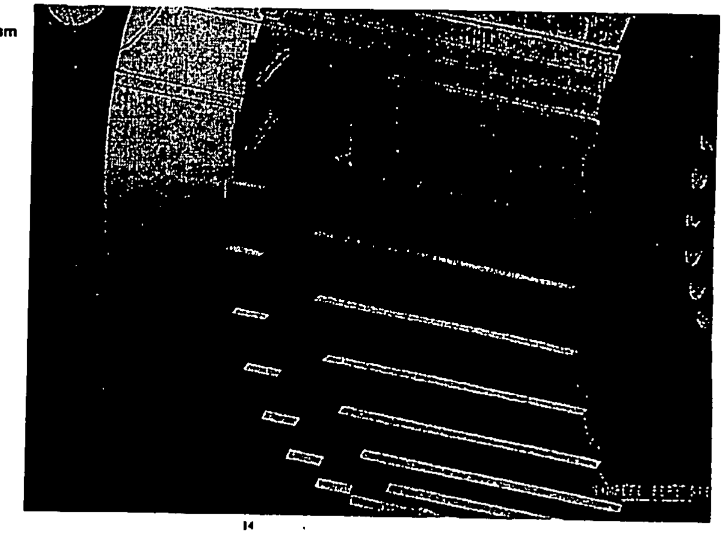
12

FIG-76



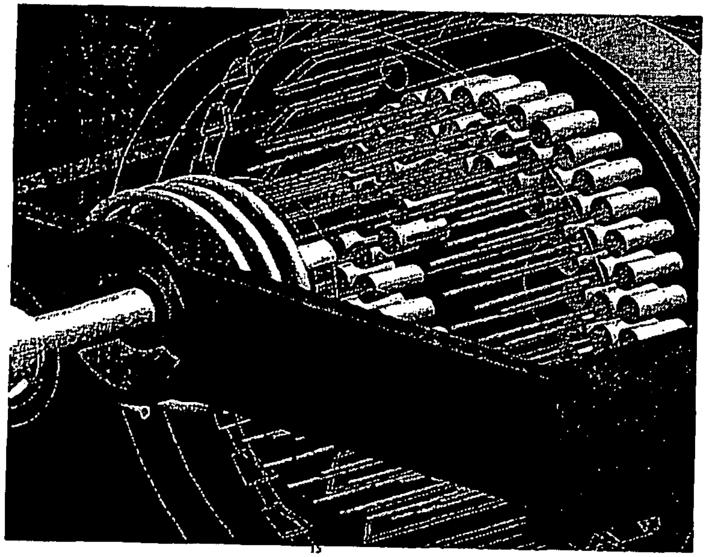
13

4. Feed mechanism

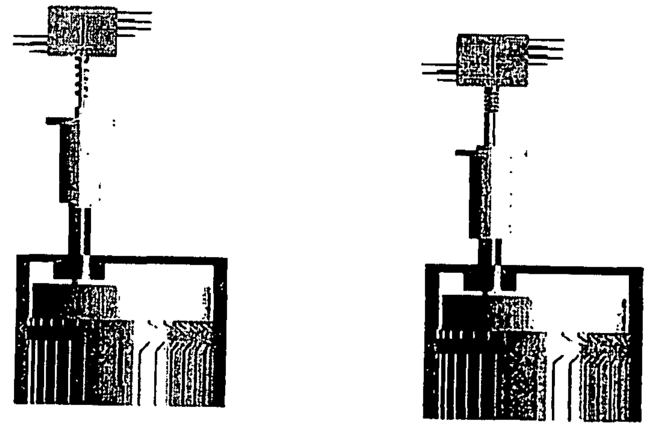


14

FIG-77



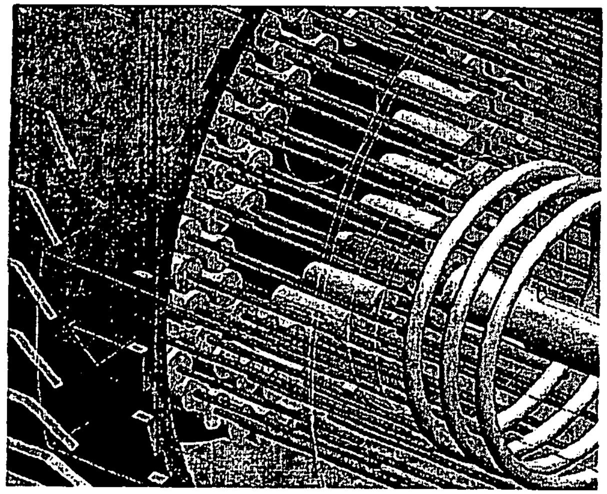
15



User actuator (red) pulled back to select new lancet

16

FIG. 78



Collet opens to accept lancet rotating in from side



5. Lancet fire

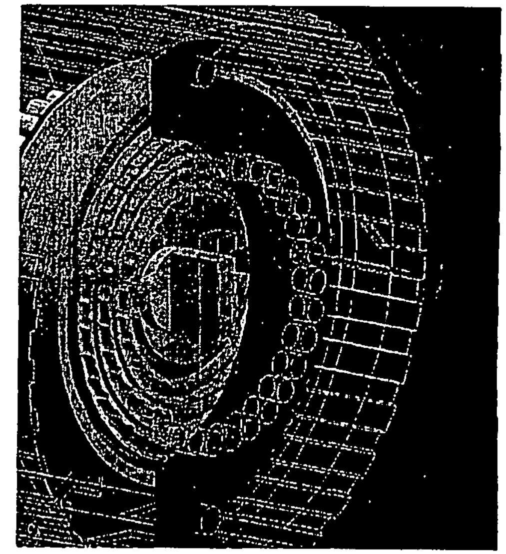


FIG-79

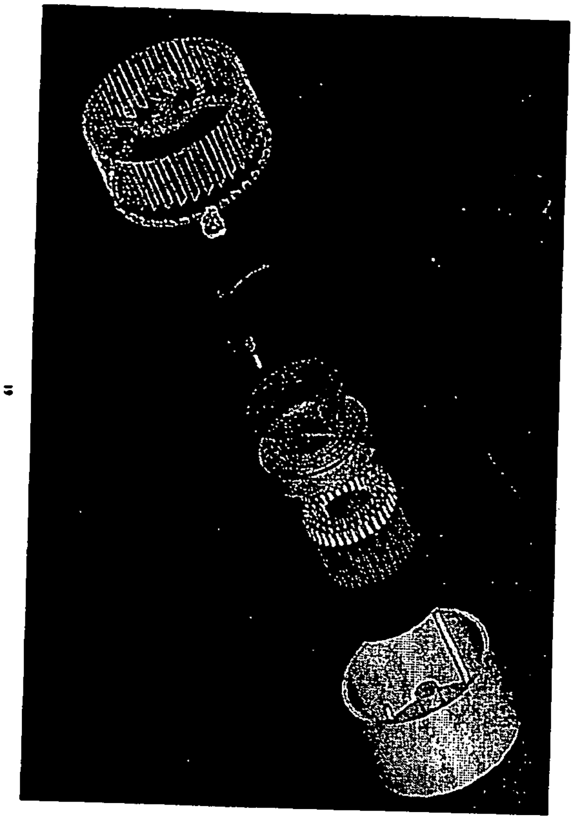


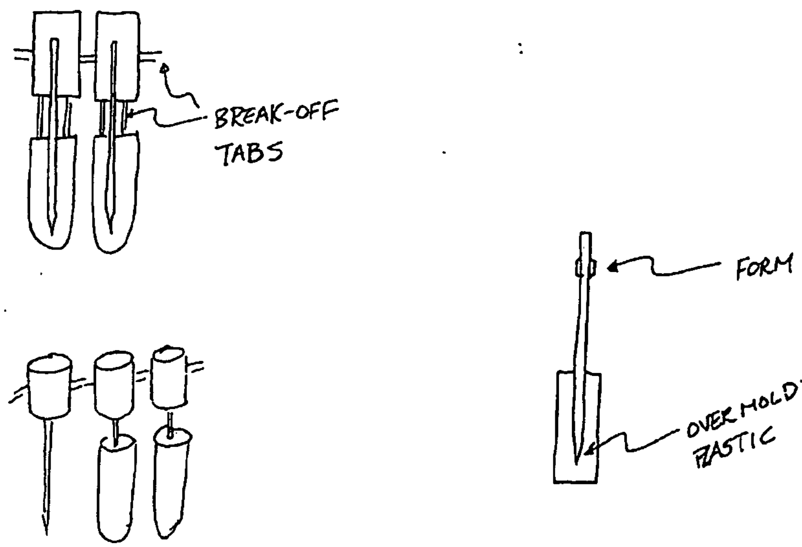
FIG_80

# Lancet Concept Selection: Top 5

On all of these options, consider:

- How complex would the advance mechanism be?
- How is cover stripped off?
- Where does cover go?
-

Option 1: Overmolded lancet



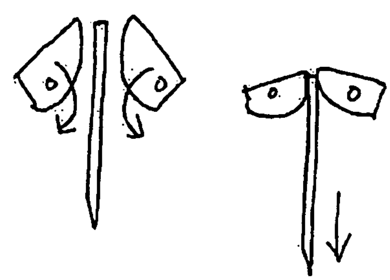

This is one of the safest options on the table since it is an extension of existing technology. The tops may or may not be overmolded. The lancets may or may not be connected. Design challenges are ahead in the designing the right strength for the connecting tabs and the stripping and advancing mechanism.

Where do stripped off plastic covers go?

1) Manufacturable – who? What process?
   Current lancet manufacturers
2) Cost estimate
3) Sterility
4) Transport mechanism

FIG_81

# Mechanism Concepts



Concept Ref #: D1
Concept Name: Cam

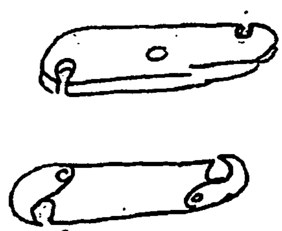
Summary: Cam with "grippy" sides rotate to grip lancet and force forward.

Key Ideas
- Lancet is gripped by friction.
- Cam design automatically releases lancet.

Advantages
- Lancet does not need gripping feature on head.

Disadvantages
- Lancet may slip without mechanical engagement.

Risk: Low – Medium
Size: Medium
Cost: N/A




Concept Ref #: D2
Concept Name: Rotary Claws

Summary: Claws spin around. Can stop at discrete positions for pick-up, use, and disposal. Claw design has normally open claws that close around needle when it hits a ramp.

Key Ideas
- Close claws on lancet to grip.
- Discrete areas for clean, use, dirty.

Advantages
- Can pick up/drop off in different areas.
- Good mechanical engagement.

Disadvantages
- Claws may clog with contaminants.
- Small moving parts may be difficult to assemble.

Risk: Medium
Size: Medium
Cost: N/A



FIG_82

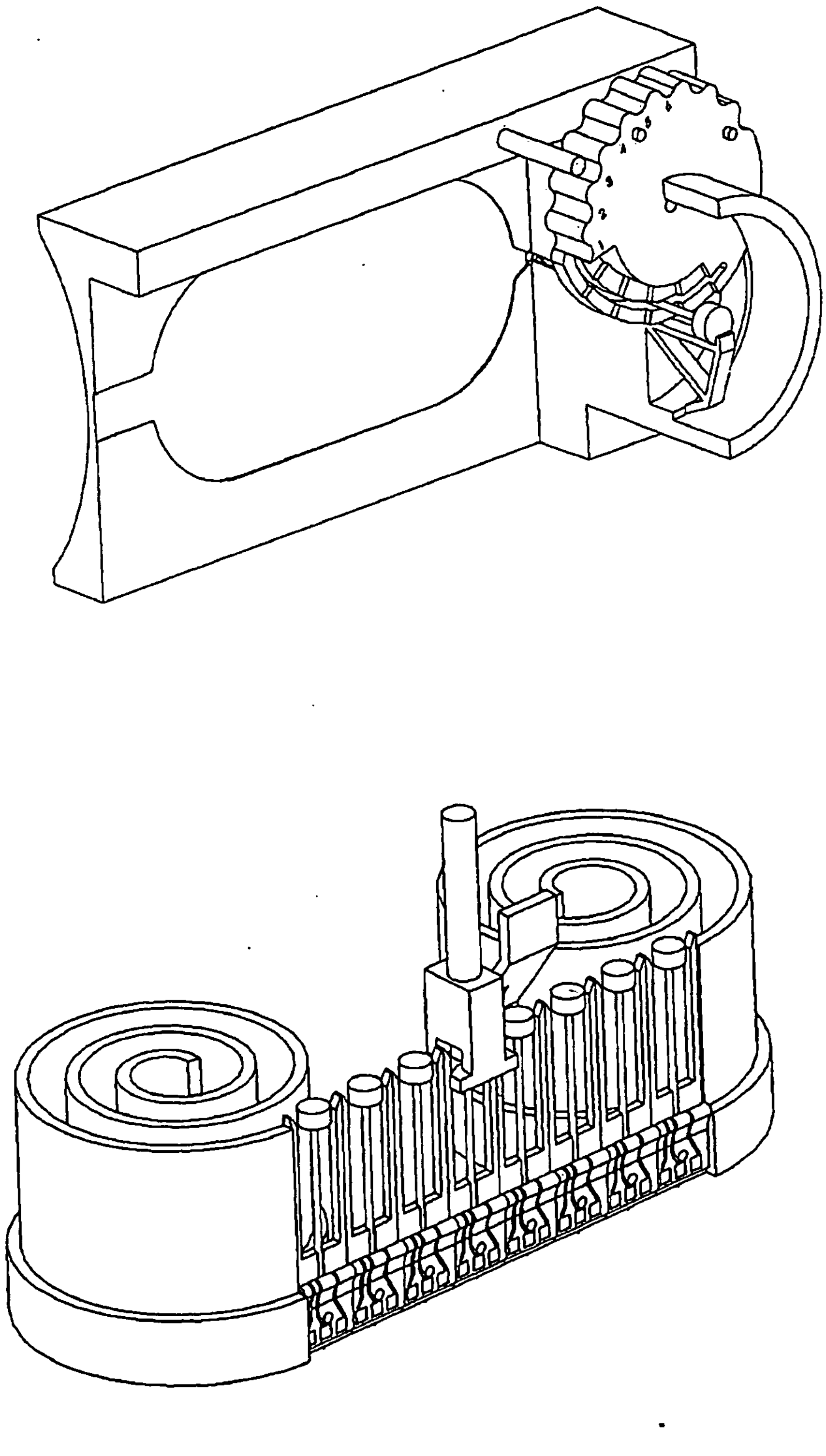


FIG_83

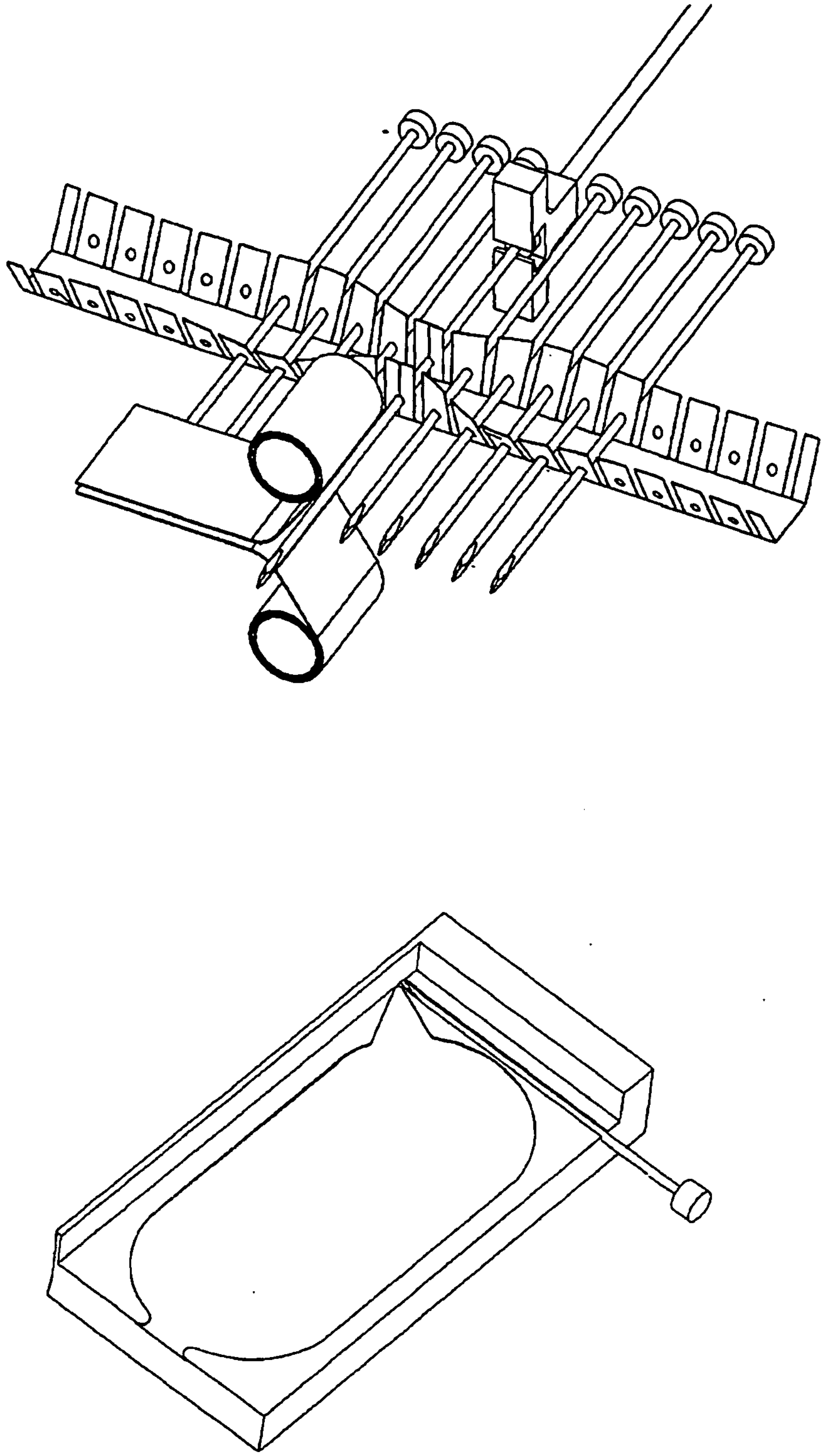


FIG-84